Health Canada Santé Canada

*PROTECTED WHEN COMPLETED*

# Health Canada's Special Access Programme (SAP)
# Instructions for Filling out a Follow-up Form
# FORM C

**SECTION A: PRACTITIONER 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/Clinic:** Name of Hospital or Clinic where practitioner works and where the patient was/is being treated.

**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.

**Date Drug Requested?:** When was the original request made.

**SECTION B: PATIENT INFORMATION**

**Initials:** First, middle (if applicable) and last initials of the patient **Note**: To ensure patient confidentiality, please do not indicate the patient's full name.

**DOB:** specify the date of birth in order of date, month, year (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 was requested.

**SECTION C: DRUG INFORMATION**

**Trade Name/Generic Name:** Full name of drug, including when possible, both trade and generic names.

**Route of Administration:** Specify the route of administration.

**Dosage Form:** Specify the dosage form.

**Current Dosage:** What is/was the most recent dose administered.

**Has the dose been altered?:** Specify whether the dose has been modified from what was included on the original request

**Start treatment date?:** Specify the date when treatment was started.

**Is treatment ongoing?:** Check the appropriate box. If No, specify the date when treatment was stopped.

**Reason for discontinuation:** Provide details on why the treatment was stopped.

**SECTION D: TREATMENT RESPONSE**

**What was the goal of the treatment?:** Provide details on what goals were set out to be achieved with this drug.

**Response to treatment:** Check the applicable box.

**Describe the response:** Provide details on how the patient responded to treatment with this drug- including positive and negative responses.

**Concomitant medications:** List all other medications the patient is/was on while on treatment with this drug.

**SECTION E: SAFETY-ADVERSE REACTIONS**

**Did the patient experience any serious and unexpected adverse reactions*?** Check of the applicable box. If the answer is YES, please fill out a Council for International Organizations of Medical Science (CIOMS) Adverse Reaction form. The form can be accessed at: www.**cioms**.ch/**cioms**.pdf

**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.

*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.

# SPECIAL ACCESS PROGRAMME
# FORM C -PATIENT FOLLOW-UP FORM

| SECTION A: PRACTITIONER INFORMATION | |
|---|---|
| Practitioner's Name: | Tel: |
| Hospital/Clinic: | Fax: |
| Date Drug Requested? | |

| SECTION B: PATIENT INFORMATION | | |
|---|---|---|
| Patient Initials: | DOB: | Sex: Male ❑ Female ❑ |
| Indication for Use of Drug: | | |

| SECTION C : DRUG INFORMATION | |
|---|---|
| Trade Name: | Generic Name: |
| Route of Administration: | Dosage Form: |
| Current Dosage: | |
| Has the dose been altered? No ❑ Yes ❑ Reason (s): | |
| Start Treatment Date: | Is treatment ongoing? Yes ❑ No ❑ Stop Treatment Date: |
| Reason for discontinuation: | |

| SECTION D: TREATMENT RESPONSE | | |
|---|---|---|
| What was the goal of treatment? | | |
| Response to treatment: None ❑ Partial ❑ Complete ❑ | | |
| Describe response: | | |
| Concomitant Medications or Therapies: | | |
| | | |
| | | |

## SECTION E: SAFETY - ADVERSE REACTIONS

Did the patient experience any serious and unexpected adverse reactions*? Yes ❑ No ❑

**If you answered YES to the above question, please fill out a Council for International Organizations of Medical Science (CIOMS) Adverse Reaction Form. The form can be accessed at: www.cioms.ch/cioms.pdf**

**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.

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