**Special Access Program Requests**

##  **PRINCIPLE**

1. The Special Access Program (SAP) of Health Canada provides access to non-marketed (not licensed for distribution in Canada) drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. 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 not approved for sale in Canada and not on the formulary of Canadian Blood Services.
2. The Canadian Blood Services (CBS) Head Office will supply a list of products requiring an SAP request form.

## **PURPOSE**

* 1. To provide a procedure for requesting access to non-marketed drugs for patients.

## **RELEVANT REQUIRMENTS**

* 1. SAP authorization does not constitute an opinion or statement that a drug is safe, efficacious or of high quality. SAP does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations of the manufacturer respecting safety, efficacy and quality.10.1
	2. 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. 10.1
	3. The SAP strongly encourages practitioners treating individuals with drugs obtained through the SAP to seek informed consent before treatment.10.1
	4. In seeking and receiving access to a drug through the SAP, the practitioner agrees to provide both the SAP and the manufacturer with a report on the use of the drug, including information on adverse reactions and, on request, account for all quantities of drug received.10.1

## **RELATED POLICIES/PROCEDURES *(POLICIES IN OTTRM)***

1. [Glossary of Terms and Abbreviations](https://orbcon1.sharepoint.com/%3Aw%3A/s/Goal2/EXQIO0FaXtxGjJ3ZUyEONuQBvYmlPZcjkguZRSZmouJNsw?e=5nMATg)

## **MATERIALS**

1. **Specimen – N/A**
2. **Equipment – N/A**
3. **Reagents – N/A**
4. **Supplies/Related Forms**
	1. Supplies: [Special Access Request form (Health Canada)](https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html)

## **QUALITY CONTROL – N/A**

## **PROCEDURE**

| **STEPS** | **WORK INSTRUCTIONS** |
| --- | --- |
| * 1. Receive request from physician
 | * + 1. Receive request

|  |  |
| --- | --- |
| If | Then ensure that  |
| Request is received by requisition | patient’s demographics are listedphysician name is listedproduct and dosage required is listedtime of receipt of requisition is indicated |
| Request was received from LIS | request is printedpatient’s demographics are listedphysician name is listedproduct and dosage required is listed |

 |
| 7.2 Request physician to complete SAP form | * + 1. Request the Physician to complete the SAP Request form and return to the Transfusion Service Laboratory. Access the most current version at https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/special-access/drugs/special-access-program-form-a-patient-specific-request-c08-010-1-en.pdf. Instructions for the physician are included with the form.
 |
| * 1. Receipt of completed form
 | * + 1. Upon receipt of the completed form fax it immediately to the SAP contact number identified on the form as per instructions included in the form. Telephone calls should be reserved for urgent requests requiring immediate attention.
 |
| * 1. Inform local blood supplier
 | * + 1. Inform your local CBS distribution site of the request to SAP. This can be done by telephone (document call) or by faxing a blood order form to the centre with the notation: The following Products/Volumes have been requested from SAP. Then list the products/volumes.
 |
| * 1. Receive products
 | * + 1. The products will be shipped from CBS when the Health Canada approval is received. During regular working hours use your routine delivery schedule (unless patient requires the product urgently). After hours the emergency issue procedures will be followed.
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## **PROCEDURE NOTES**

* 1. **SAP Contact Information:**

The SAP business hours are 8:30 am to 4:30 pm E.S.T., Monday to Friday. An **On Call service is available after-hours for emergency situations by telephoning (613) 941-2108**. Calls to this number should be limited to requests requiring immediate or overnight drug delivery.

**Fax**: (613) 941-3194

**Tel**: (613) 941-2108

**E-mail**: SAPdrugs@hc-sc.gc.ca

**Web Site**: [http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-eng.php%20)

**Mailing Address:**

Therapeutic Products Directorate

Finance Building, 2nd Floor

PL 0202C1, Tunney's Pasture

Ottawa, ON, K1A 1B9

## **REFERENCES**

* 1. Health Canada - Special Access Program for drugs: Guidance document for industry and practitioners [Internet] available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs/guidance.html#a22>

## **REVISION HISTORY**

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| --- | --- |
| Revision Date | Summary of Revision |
| August 8, 2014 | * Revised name of manual
* Revised section 6.0
* Revised list of references
 |
| July 16, 2021 | * Revised link to form
* Revised contact number
* Formatted to new SOP template
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