1. **Principle**

The Special Access Program (SAP) provides access to non-marketed 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.

The Canadian Blood Services (CBS) Head Office will supply a list of products requiring a SAP request form.

1. **Scope and Related Policies**
	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.
	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.
	3. The SAP strongly encourages practitioners treating individuals with drugs obtained through the SAP to seek informed consent before treatment.
	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.
2. **Specimen – N/A**
3. **Materials**

**Supplies:** Special access request form from Health Canada

1. **Quality Control – N/A**
2. **Procedure**

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| * 1. When informed that a product that is on the Special Access Program (SAP) is being requested you must alert the Physician that the product is only available through SAP.
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| * 1. Request a requisition with patient’s stamped addressograph, Dr.’s name, product required and dosage. Record time of receipt on requisition.
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| * 1. Request the Physician to complete the SAP Request form and return to the Transfusion Service Laboratory. Access the most current version at <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapf1_pasf1-eng.pdf>. Instructions for the physician are included with the form.
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| * 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.
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| * 1. Inform your local blood center of the request to SAP. This can be done by telephone (document call) or by faxing a blood order form to the center with the notation: The following Products/Volumes have been requested from SAP. Then list the products/volumes.
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| * 1. The products will be shipped from CBS when the 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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**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) 941-3061.** 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>

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| **Mailing Address:** | Therapeutic Products Directorate Finance Building, 2nd Floor PL 0202C1, Tunney's Pasture Ottawa, ON, K1A 1B9 |

1. **Reporting – N/A**
2. **Procedural Notes – N/A**
3. **References – N/A**
4. **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
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