SPECIAL ACCESS PROGRAMME - DRUGS

What is the Special Access Programme?

The Special Access Programme (SAP) allows practitioners to request access to drugs that are unavailable for sale in Canada. This access is limited to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable.

Can SAP be considered a fast-track approval process for drugs?

No. SAP is not intended to be a mechanism to promote or encourage the early use of drugs or to circumvent the clinical trials review and approval process or the new drug approval process, but rather to provide compassionate access to drugs on a patient by patient basis.

Are there any SAP regulations or policies - and if so where can I find them?

The SAP is supported by sections C.08.010 and C.08.011 of the *Food and Drug Regulations*. In the future, a guidance document will be available on the SAP website which provides more detail on the day to day operations of the SAP.

What types of drugs and for what conditions could be authorized under the SAP?

These range from pharmaceutical, biologic, and radiopharmaceutical products that are not approved for sale in Canada. Most of these drugs treat patients with life threatening diseases or serious conditions such as intractable depression, epilepsy, transplant rejection, hemophilia and other blood disorders, terminal cancer, and AIDS. The SAP can also respond to specific health crises, such as an outbreak of a communicable disease, by providing access to nonmarketed drugs.

Is there a list naming the drugs that can be released through the SAP? If yes, is it available to the public?

The Special Access Management System (SAMS) is an internal database that lists all drugs eligible through the SAP. This list changes continuously making a current publication difficult to maintain. Practitioners interested in the status of a particular drug may contact the manufacturer or the SAP.

What is the practitioner's role in the SAP?

The practitioner is responsible for initiating a request on behalf of a patient and ensuring that the decision to prescribe the drug is supported by credible evidence available in the medical literature or provided by the manufacturer. It is also the practitioner's responsibility to ensure that patients are well informed of the possible risks and benefits of the drug being requested.

How do practitioners request access to a SAP drug?

A *Special Access Request (SAR) Form* and associated instructions are available on the Health Canada web site (see contact information below). The *SAR Form* consists of two pages containing five sections. Practitioners are required to complete all five sections of the form. Completed forms should be faxed to the SAP **without** an accompanying cover sheet. Telephone calls should be reserved for urgent requests requiring immediate attention.

Are there any restrictions on the amount a practitioner can request?

A maximum quantity equivalent to a six month duration may be authorized for chronic treatments. Repeats must be re-ordered through the usual SAP request procedures.

What assurance does the SAP give to the patient that the drug that they are receiving is safe?

The SAP authorization does not constitute an opinion or statement that a drug is safe, efficacious or of high quality. The SAP does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations from the manufacturer respecting safety, efficacy and quality. We consider these important factors for practitioners to consider when recommending the use of a drug and in making an appropriate risk/benefit decisions for their patients.

What is the processing time for a SAP request?

Every effort is made to process requests within 24 hours of receipt. However, given the mandate of the Programme and the volume of SARs received, the SAP adopts a triage system to ensure that requests for drugs for life-threatening conditions take precedence over other less urgent matters. If a drug is new to the Programme, the total processing time may be extended, although every effort is made to contact the practitioner within 24 hours to discuss the process for handling new products.

How are requests processed?

Authorized *SARs* are sent by facsimile to manufacturers and entered into the SAMS database from which formal Letters of Authorization are issued. These formal letters are signed and sent by surface mail to the manufacturer and copied to the practitioner.

Are all requests authorized?

Following careful consideration of the *SAR*, the SAP will either grant or deny authorization. *SAR's* that are denied authorization are returned by fax to the practitioner with an explanation. SAP may also contact the practitioner by telephone to discuss the reasons for the denial and what, if any, recourse the practitioner may consider.

What is the manufacturer's role in SAP?

In all cases, the manufacturer has the final word on whether the drug will be supplied. The manufacturer has the right to impose certain restrictions or conditions on the release of the drug to ensure that it is used in accordance with the latest information available. For instance, they may restrict the amount of product released, request further patient information, determine payment requirements and place conditions on shipping arrangements. Manufacturers are also responsible for providing all drug information to requesting practitioners and/or patients.

Are there any restrictions on where the drug can be shipped?

SAP drugs may only be sent to the practitioner's office or in-patient pharmacies . Manufacturers are not permitted to send SAP drugs to retail pharmacies.

Who pays for the drugs being released though SAP?

While there is no requirement for manufacturers to provide drugs released through the SAP free of charge, many do. When manufacturers do charge, the cost is covered by either the patient, the patient's family, the hospital, a public and/or private insurance plan.

Are there reporting requirements after a practitioner uses a drug released through the SAP?

The practitioner must agree to provide a report on the results of the use of the drug, including any adverse reactions. It is imperative that practitioners keep accurate and accessible records in the event that the SAP requests an accounting for quantities of the drug received.

What are the SAP's Operational Hours?

SAP operates 24 hours a day, 365 days a year. Regular business hours are from 8:30 am to 4:30 pm Eastern Standard Time. On call service after-hours for emergency situations is available from 4:30 pm to 8:30 am on weekdays. On weekends service is provided from 4:30 pm on Friday until 8:30 am on Monday except during statutory holidays when the service continues until 8:30 am on the first business day following the holiday.

Contact Information

Special Access Programme
Therapeutic Products Directorate
2nd Floor, Holland Cross, Tower A
11 Holland Ave., A.L. 3002C
Ottawa, ON, K1A 0K9

TEL: (613) 941-2108 **FAX:** (613) 941-3194

E-MAIL: SAPdrugs@hc-sc.gc.ca
WEB SITE:
http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index_e.html