Health Canada Santé Canada

Special Access Programme – Drugs

1. What is the Special Access Programme?
Health Canada's Special Access Programme (SAP) considers requests for access to drugs that are unavailable for sale in Canada from practitioners treating patients with serious or life-threatening conditions when conventional treatments have failed, are unsuitable or unavailable.

2. 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*. Additional information on the Programme and *Regulations* is provided in Health Canada's *Guidance Document for Industry and Practitioners - Special Access Programme for Drugs.* The *Guidance* document is available on the Health Canada website (http://www.healthcanada.gc.ca/sap).

3. What types of drugs are considered via the SAP?
Some non-marketed drugs may be accessed by practitioners for the treatment, diagnosis or prevention of serious or life-threatening conditions via the SAP in some circumstances where all marketed alternatives have been exhausted and sufficient evidence supports the specified use. For example, access to some blood products for emergency treatment of hemophilia is considered via the Programme. Additional information on the consideration process is available in Section 4 of the *Guidance*.

4. What products are outside the scope of SAP-drugs?
Drugs that are or that contain a "restricted drug" as defined in Part J of the *Food and Drug Regulations* are **not** eligible for authorization via the SAP as per subsection C.08.010 (1.1) of the *Regulations*. Veterinary products, medical devices, marijuana for medical purposes and drugs for research are requested via other programs (http://www.hc-sc.gc.ca/contact/dhp-mps/index-eng.php).

5. Is there a list of drugs that can be released via the SAP?
Due to its ever-changing nature, there is no externally available list of products accessible via the SAP. Practitioners interested in the status of a particular drug may contact the SAP (see contact information below).

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6. What is the practitioner's role?
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 (generally no older than 10 years) 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 and its development status. The practitioner must agree to provide a report on the results of the use of the drug, including any adverse reactions. The SAP is intended for emergency access; it is expected that the collection of clinical data with respect to the drug will only be used to monitor the patient's condition.

The collection of data for research purposes should be done under a clinical trial which is subject to other regulatory provisions under the *Food and Drug Regulations* (Part C, Division 5). Regarding drug supplies, practitioners must also keep accurate and accessible records in the event that the SAP requests an accounting for quantities of the drug received. Additional information on reporting and record keeping is listed in Section 6 of the *Guidance*.

7. What defines a practitioner in the context of SAP?
A "practitioner" is an individual who is entitled under the laws of a province to treat patients with a prescription drug under the *Regulations*. In most cases, this would be a provincially licensed physician. Given evolving roles in health care, in some cases other provincially licensed health professionals may submit requests for consideration to the SAP. Health professionals should consult their professional college for information on the scope of practice.

8. How do practitioners request access via the SAP?
Practitioners can submit requests using a Special Access Request (SAR) Form. The 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 to (613) 941-3194. Telephone calls should be reserved for urgent requests requiring immediate attention. Additional information on the request process is available in Section 3 of the *Guidance*. The forms and associated instructions are available on the Health Canada website (http://www.healthcanada.gc.ca/sap).

9. Are there any restrictions on the amount of drug a practitioner can request?
Most drugs accessed via the SAP are for acute serious or life-threatening conditions that require short term treatment. For chronic conditions, quantities equivalent to a maximum of a six month supply may be considered per request.

10. Is an SAP authorization an assurance of safety and efficacy of a drug?
All products have some level of known and unknown risk. Generally, as a product advances in development, risks and benefits are often better characterized (Does the drug work? Is it safe? What are the side effects?). The SAP employs a risk management process that takes into account the known risks of the product, marketed alternatives, manufacturing standards, product information provided by the manufacturer, the stage of development as well as level of evidence for use in a condition. However, an SAP authorization is **not** equivalent to a market authorization, it does not constitute an assurance that a drug is safe, efficacious or of high quality. These are important factors for practitioners to consider when recommending the use of a drug and in making an appropriate risk/benefit decision for their patients.

11. Can SAP be considered a fast-track approval process for drugs or research?
No. SAP is not intended to be a mechanism to promote or encourage the early use of drugs or to conduct research or to circumvent the clinical trial or drug review process. To pursue clinical research or marketing of a drug in Canada, a sponsor (for example, a person or company) must submit an application for regulatory review. For information on these applications, please contact the applicable review bureau (http://www.hc-sc.gc.ca/contact/dhp-mps/index-eng.php).

12. 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 that require timely administration take precedence over other less urgent matters. If a drug is new to the Programme, the total processing time will be extended, although every effort is made to contact the practitioner within 24 hours to discuss the process for handling new drugs.

13. How are requests processed?
When a SAR is received, it is screened and reviewed. Following careful consideration, the SAP will issue one of the following decisions:

- **Authorization**: Information provided meets the criteria of the Programme.
- **Incomplete**: The SAR form is incomplete, missing information or is illegible. The SAR is returned with an incomplete notification to the practitioner.
- **Cancellation**: Due to external or logistical factors, the requested drug is not accessed via the SAP. For example, the manufacturer is unable to provide access via the SAP.
- **Withdrawal**: The SAR is withdrawn by the requesting practitioner.
- **Denial**: The information provided by the practitioner does not meet the criteria of the Programme, or the request was returned as incomplete numerous times and information is still lacking.

If a request is authorized, a Letter of Authorization is sent by fax to the manufacturer and a copy sent to the practitioner. If not authorized, the SAP issues a letter only to the practitioner with an explanation. The SAP may also contact the practitioner by telephone to discuss the reasons for the decision. Additional information on the consideration process is available in Section 4 of the *Guidance*.

14. What is the manufacturer's role in SAP?
Drugs accessed via SAP are supplied directly by manufacturers to practitioners. When a SAP authorization is issued, 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, indications for which access will be provided, request further patient information and place conditions on shipping arrangements. Manufacturers are also responsible for providing all drug information to requesting practitioners. Additional information on roles and responsibilities is listed in Section 2 of the *Guidance.*

15. Who pays for the drugs being released via SAP?
Although there is no requirement for manufacturers to provide drugs released via 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 or insurance plans.

16. Are there any restrictions on where the drug can be shipped?
The drug supplies authorized by the SAP can only be sent to the requesting practitioner's office, in-patient pharmacies, radiopharmacies or blood banks. Manufacturers are not permitted to send these supplies to retail pharmacies.

17. Who can be contacted for information on importation or shipments at borders?
Questions on personal or commercial importation requirements of health products in Canada should be directed to the Health Products and Food Branch Inspectorate (http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/hpfb-dgpsa-eng.php).

18. What are the SAP's Operational Hours?
The SAP can be reached 24 hours a day, 365 days a year. Regular business hours are from 8:30 am to 4:30 pm Eastern Standard Time on weekdays. On call service is available for emergency situations outside of business hours, weekdays from 4:30 pm to 8:30 am, weekends from 4:30 pm on Friday to 8:30 am on Monday except during statutory holidays when the on call service continues until 8:30 am on the first business day following the holiday.

Contact Information

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