Health Canada Santé Canada

December 20, 2013

NOTICE

Our file number: 13-119188-196

Final Special Access Programme (SAP) for drugs Guidance Document

This document provides guidance on access to unauthorized drugs through the SAP and clarifies the mandate, intent and scope of the Programme. It outlines the process to be followed when requesting a drug through the SAP, as well as the information required to comply with Sections C.08.010 and C.08.011 of the *Food and Drug Regulations*.

This document has been updated as a result of amendments to the *Food and Drug Regulations* published in Canada Gazette Part II on June 19, 2013. The *Regulations Amending Certain Regulations concerning Prescription Drugs* (Repeal of Schedule F to the *Food and Drug Regulations*) provides for the repeal of Schedule F and incorporation by reference of a list of prescription drugs. This regulatory amendment comes into effect on December 19, 2013.

As a result of this amendment, a number of existing Guidance Documents have been identified that make reference to Schedule F and the regulatory process for assigning prescription status. Due to the replacement of Schedule F with the Prescription Drug List and the replacement of a regulatory process with an administrative process, the identified Guidance Documents required updating.

The Document Change Log has been added to reflect the changes.

Questions or concerns related to the *Guidance Document for Industry and Practitioners - Special Access Programme for Drugs* should be directed to:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Holland Cross, Tower B
Address Locator 3102C5
1600 Scott Street
Ottawa, Ontario
K1A 0K9

Tel.: 613-941-2108
Fax: 613-941-3194
E-mail: sapdrugs@hc-sc.gc.ca

Canada

Health Canada Santé Canada

GUIDANCE DOCUMENT FOR INDUSTRY AND PRACTITIONERS

Special Access Programme for Drugs

Published by authority of the
Minister of Health

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health related to health products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : Programme d'accès spécial - médicaments

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Document Change Log			
Version	Guidance for Industry: Special Access Program for Drugs	**Replaces**	Guidance for Industry: Special Access Program for Drugs
Date	December 19, 2013	**Date**	January 28, 2008

Change	Nature of and/or Reason for Change
December 19, 2013 Revision in Appendix A	Changes were made to the document to reflect an amendment to the *Food and Drug Regulations* that replaced Schedule F with Prescription Drug List.

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1 INTRODUCTION

1.1 Policy Objectives

To ensure that requests for special access to unauthorized[1] drugs are received, processed and decided upon effectively, consistently, and in accordance with sections C.08.010 and C.08.011 of the *Food and Drugs Regulations*.

1.2 Policy Statements

Health Canada is authorized under the *Food and Drugs Act* to regulate the safety, efficacy and quality of therapeutic products, including drugs (pharmaceuticals, radiopharmaceuticals, biologics and genetic therapies), natural health products andmedical devices. Prior to market authorization of a drug, access is usually limited to clinical trials sponsored by a manufacturer or research organization, and authorized by Health Canada through a clinical trial application. On those occasions when a drug is not available through enrollment in a clinical trial, Health Canada may allow an exemption from the *Food and Drugs Act* and its *Regulations* to permit the sale[2] of an unauthorized drug for a medical emergency.

Special access by Canadian health practitioners to unauthorized drugs is intended for serious or life-threatening conditions where conventional therapies have failed, are unsuitable, or are unavailable either as marketed products or through enrollment in clinical trials. Emergency access should be exceptional and where possible, open label or compassionate access trials should be incorporated into drug development plans to meet the needs of patients not eligible for enrollment in other pivotal trials.

The Special Access Programme (SAP) considers requests from practitioners for access to unauthorized drugs for treatment, diagnosis, or prevention of serious or life-threatening conditions when conventional therapies have been considered and ruled out, have failed, are unsuitable or unavailable. The regulatory authority supporting the Programme is discretionary and a decision to authorize or deny a request is made on a case-by-case basis by taking into consideration the nature of the medical emergency, the availability of marketed alternatives and the information provided in support of the request regarding the use, safety and efficacy of the drug. If access is granted, the practitioner agrees to report on the use of the drug including any adverse events encountered with such use and, upon request, account for all quantities received.

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[1] The term "unauthorized" used throughout the document implies that sale of the drug has not commenced, pursuant to C.01.014 or that the product has been discontinued or removed from the market pursuant to C.01.014.6 and C.08.006 of the *Food and Drug Regulations*.

[2] According to the *Food and Drugs Act*, "sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

The SAP is neither a mechanism to encourage the early use of drugs nor is it meant to circumvent clinical development of a drug or regulatory review of a submission for marketing. Access to any drug through the SAP should be limited in duration and quantity to meet emergency needs only. In the event that a drug submission is under regulatory review, access should be limited until that review is complete. Manufacturers should anticipate exceptional demand for a drug and, where possible, incorporate open-label or compassionate access clinical trials into their development plans to meet the needs of patients who might be ineligible for enrollment in other pivotal trials. Drugs accessed through the SAP do not undergo the scrutiny of a benefit-risk assessment provided within the regulatory framework applied to new drug submissions or clinical trial applications. Accordingly, authorization through SAP does not constitute an opinion that a drug is safe, efficacious or of high quality. Furthermore, an authorization through the SAP does not compel a manufacturer to sell a drug.

1.3 Scope and Application

This guidance document is intended to clarify the mandate, intent and scope of the SAP and outline:

- the process to be followed to access a drug that cannot otherwise be sold or distributed in Canada;
- the responsibilities of the practitioners, manufacturers, and Health Canada in that process;
- the information required to comply with Sections C.08.010 and C.08.011 of the *Food and Drug Regulations*.

For the purposes of this guidance document, "drugs" include pharmaceuticals, radiopharmaceuticals, biologics and natural health products[3]. It excludes medical devices[4], veterinary drugs[5] and active pharmaceutical ingredients (APIs)[6].

3 The Natural Health Products (NHPs) finds its authority under the *Natural Health Products Regulations*, however an amendment to the regulations permits sections C.08.010 and C.08.011 of the *Food and Drug Regulations* to apply to NHPs (*Regulations Amending the Natural Health Product Regulations (Special Access),* SOR/2004-119, May 11, 2004).

4 The Medical Device Bureau administers its own Special Access Programme and has its own Special Access Regulations contained in the *Medical Devices Regulations*. Information on how to access a medical device through the Programme is available on the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/index-eng.php)

5 The Veterinary Drugs Directorate finds its authority under sections C.08.010 and C.08.011 of the *Food and Drug Regulations* and administers a similar programme called Emergency Drug Release (EDR). Information on the Veterinary EDR is available on the Veterinary Drugs Directorate website (http://www.hc-sc.gc.ca/dhp-mps/vet/edr-dmu/index-eng.php).

6 Active Pharmaceutical Ingredients (APIs) for pharmaceutical compounding are subject to the requirements of the *Food and Drug Regulations*, Division 1A - Establishment Licensing and Division 2 - Good Manufacturing Practices (GMP).

1.4 Background

The regulatory authority to permit the sale of unauthorized drugs for a medical emergency was established in 1966 through an amendment to the *Food and Drug Regulations*. For many years, this authority was initially administered by the Emergency Drug Release Programme (EDRP) within Health Canada's former Health Protection Branch. The original purpose of the EDRP was to provide access to unauthorized drugs for medical emergencies on a case-by-case basis. In the 1990's, an internal evaluation of the EDRP found that the program was increasingly being used as a means to obtain broad access to drugs that were in the later phases of clinical trials or in the new drug submission review process. Consequently, the Programme's interpretation of the term "medical emergency" was expanded to include serious or life-threatening conditions and the EDRP was renamed as the Special Access Programme (SAP).

2 ROLES AND RESPONSIBILITIES

2.1 SAP

Requests are received by the SAP from practitioners seeking authorization for the sale of an unauthorized drug for their patient(s). Following careful consideration of the request, the SAP may either authorize a manufacturer to sell a drug to a practitioner, request additional information from the practitioner or deny the request.

The SAP undertakes the following risk management activities:

- emphasizing that marketed alternatives should always be considered and/or tried before considering the use of unauthorized drugs;
- recommending alternative mechanisms, such as clinical trials, to provide emergency access to unauthorized drugs;
- encouraging the exchange of information about drugs released through the SAP between manufacturers, practitioners and the SAP;
- monitoring issues and concerns pertaining to drugs available through the SAP;
- coordinating the dissemination of drug advisories, developed in conjunction with the manufacturer, for Healthcare Professionals respecting new information regarding drugs available through the SAP;
- reviewing documentation supporting emergency use of a nonmarketed drug prior to its first release through the SAP;
- working with the manufacturer to gather and document information about a drug, its development and regulatory status; and
- ensuring practitioners have access to current and relevant information respecting a drug available through the programme.

Information pertaining to the management of individual requests is outlined in Section 4.

The SAP reviews and tracks all Adverse Drug Reaction (ADR) reports submitted by either the practitioner or the manufacturer. In the case of a serious and unexpected ADR, the SAP will contact the manufacturer and recommend that information available on the drug be updated accordingly. The SAP may also contact the practitioner in the event of serious and unexpected ADRs.

2.2 Practitioners

The practitioner initiates a request and ensures that the decision to prescribe the drug is supported by credible evidence. Such evidence is usually found in an investigator's brochure, prescribing information from another jurisdiction, or publications in the medical literature.

It is recommended that practitioners provide their patients with information about the drug's potential risks and/or benefits as well as alternative therapies available. It is also recommended that practitioners seek informed consent from their patients.

The practitioner is responsible for reporting to both the manufacturer and the Director on the results of the use of the drug in the medical emergency, including any adverse drug reactions encountered. The practitioner must also, upon request, provide an accounting for all drug supplies received.

2.3 Manufacturers

Following authorization of a request by the SAP, the manufacturer is responsible for deciding whether or not to sell the drug. A manufacturer is under no obligation to sell an unauthorized drug and the SAP cannot compel a manufacturer to do so. A decision to invoice for a product authorized by the SAP rests with the manufacturer. Manufacturer s are responsible for determining price, if any, and may consult the Patented Medicines and Pricing Review Board (PMPRB) in this regard if necessary.

The manufacturer may impose conditions on the sale of a drug to ensure that it is used in accordance with the latest information available. For instance, the manufacturer may restrict the amount of the drug sold, request further patient information, or offer a protocol for the use of the drug. Manufacturers are also responsible for providing all relevant information, such as an Investigator's Brochure, to requesting practitioners.

Foreign manufacturers are responsible for ensuring that they meet the regulatory requirements of their own country with respect to the export of drugs to Canada, especially in the case of a controlled drug. In addition, Health Canada's Office of Controlled Substances must issue an Import Permit to the manufacturer. This permit allows the drug supplies to be shipped without incident into Canada and ensures that all appropriate authorities are so notified.

Manufacturers should clearly display the SAP Letter of Authorization with other related documents, such as export permits, to facilitate clearance by the Canada Border Services Agency (CBSA).

Manufacturers are expected to ensure that significant new information respecting the safety, efficacy and quality of drugs released under the SAP is made available to practitioners and the SAP expeditiously. Should new information about a drug become available in other jurisdictions, this information should be vetted through the SAP prior to communication with practitioners.

3 INITIATING A SPECIAL ACCESS REQUEST

To initiate a Special Access Request, practitioners must complete one of the following Special Access Request (SAR) Forms.

3.1 Special Access Request- Form A

The Special Access Request (SAR) Form, Form A, should be used when the practitioner is requesting patient specific access to a drug for one or multiple patient(s) when required for immediate use or in anticipation of use in the short term.

3.2 Special Access Request for Future Use- Form B

The SAR Form for Future Use, Form B, should be used to request access to a drug is required on hand in anticipation of patients presenting with a medical emergency. The practitioner should include a clinical rationale as to why it is required on hand as opposed to requesting it for specific patients.

Both forms and their associated instructions may be accessed and downloaded from the Health Canada website.

Completed forms should be faxed, or sent by mail to:

Special Access Programme
Health Canada, Tunney's Pasture
Address Locator 3105A
K1A 0K9

Telephone: 613-941-2108
Fax: 613-941-3194
E-mail: SAPdrugs@hc-sc.gc.ca

A cover sheet is not required for forms sent by facsimile. Telephone requests should be reserved for life-threatening situations requiring immediate attention. By telephone, practitioners should be prepared to provide all of the required information using the form as a guide.

3.3 After Hours Requests

To place a request outside of the SAP regular office hours (please refer to Section 5), the On Call officer should be contacted.

The On Call officer can be reached by calling the regular business line (613-941-2108) and pressing 0. The officer will either answer directlyor return the phone call within 20 minutes. The officer will determine and discuss how the request will be processed. If authorization is granted, the officer will endeavour to contact the manufacturer immediately or before the next business day. While many manufacturers have on-call services, not all are equally accessible. In circumstances where a manufacturer does not offer an On Call service, processing of the request may be delayed until the next business day.

Practitioners should submit a completed *SAR Form* to the SAP the following day.

4 SPECIAL ACCESS REQUEST (SAR) FORM PROCESSING

4.1 Screening

Most requests are processed within 24 hours of receipt. However, given the mandate of the programme and the volume of requests received, requests are triaged to ensure that urgent matters take precedence over less urgent matters. For example, requests for blood products and certain antibiotics are given priority. Screening includes ensuring that: all sections of the form are complete; the information provided is legible; a quantity of 6 months or less is requested; the practitioner has provided their license number, and the request is signed and dated. Once a request is screened, it is forwarded to an officer for review.

4.2 Consideration

Consideration is the process by which the SAP decides whether authorization is appropriate and justified. Each request represents a unique set of circumstances and is supported to varying degrees by information provided by the practitioner. Consideration takes into account and balances the following factors (Figure 1. Request Consideration Matrix) to ensure that an emergency exists and there is credible data to support the request:

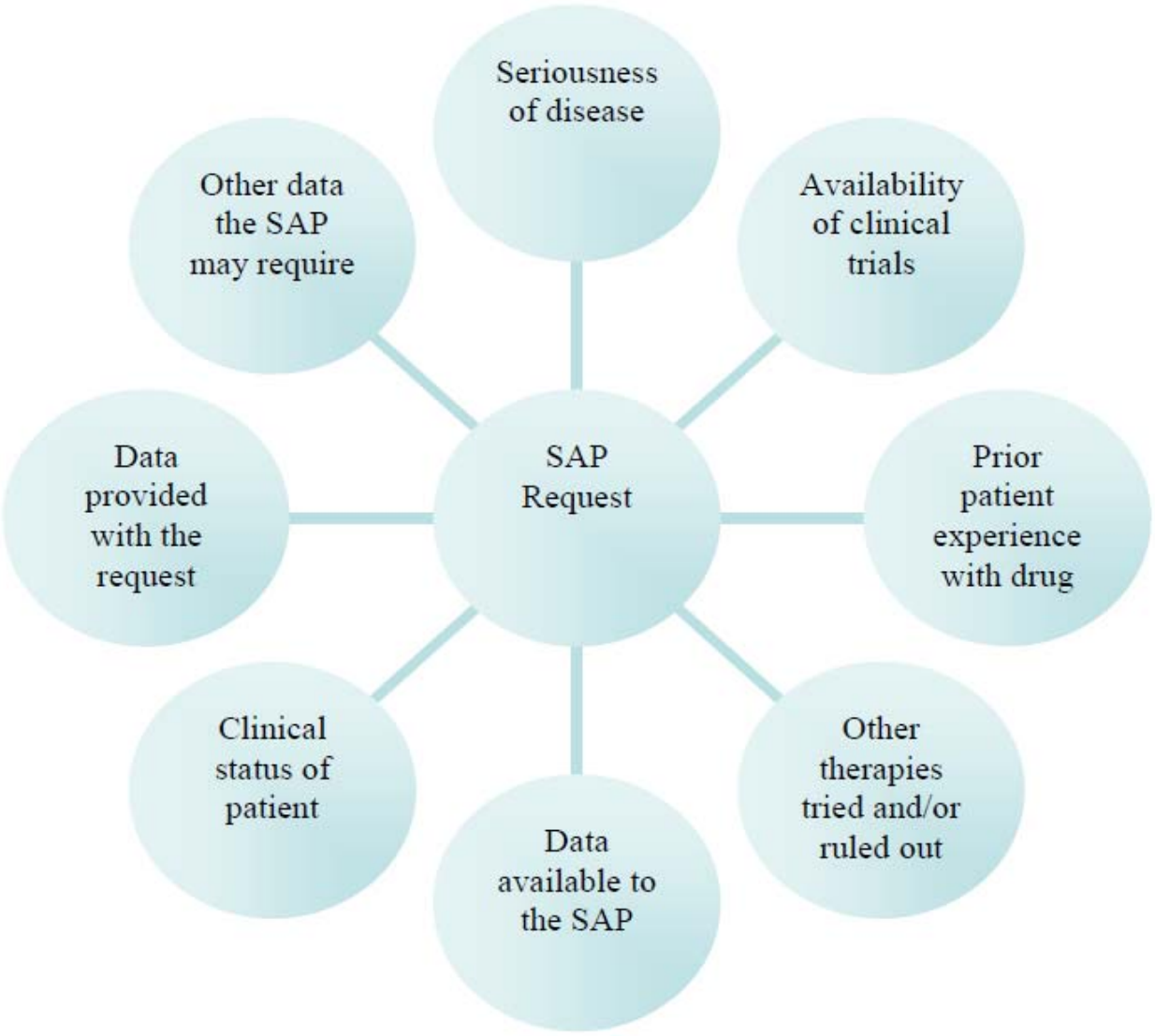

Figure 1. Request Consideration Matrix

Seriousness of disease	• description of the medical emergency for which the drug is requested
Clinical status of patient	• description of current clinical status of the patient, including prognosis
Other therapies tried and/or ruled out	• summary of marketed therapies that have failed, have been considered, ruled out or are unavailable
Prior patient experience with the drug	• summary of a patient's past experience with the drug, including evidence of efficacy and adverse drug reactions
Data provided with request	• quality and relevance of data to the medical emergency • a hierarchy of available evidence may range from: • prescribing information/package insert from the jurisdiction where the drug may be marketed • data from the literature outlining the results of randomised controlled trials • data from the literature outlining the results of non-randomised trials • case series and individual case reports from the literature **and/or**; • unpublished reports
Other data the SAP may require	• additional information from the practitioner respecting the drug or the clinical rationale
Data available to the SAP	• medical literature, treatment guidelines, investigator's brochures, information obtained from the manufacturer, clinical trial reports, consultations with Health Canada experts, etc. • consultations with expert reviewers in the Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate • confirmation of the Canadian and international development /regulatory status of the drug
Availability of clinical trials	• determine if enrollment in clinical trials is an option for an individual patient.

4.3 Special Considerations

4.3.1 Drugs that have received a negative regulatory response

The SAP will consider requests for drugs that have received a negative decision [that is (i.e.), NOD/W or NON/W] following the review of a drug submission by Health Canada or another regulatory jurisdiction provided that:

- the manufacturer agrees to disclose the concerns raised by the relevant regulator to the requesting practitioner(s).
- the manufacturer drafts a letter to requesting practitioners that includes the main concerns from the withdrawal letter.
- the relevant review bureau at Health Canada verifies that the concerns are well described.

These steps ensure that requesting practitioners and their patients are aware of all relevant information respecting the drug required to make an informed decision about its use.

4.3.2 Marketed drugs with compliance actions

The SAP will consider authorizing access to drugs following compliance action provided that:

- the drug is considered to be medically necessary for the treatment, diagnosis or prevention of a serious or life-threatening condition;
- the manufacturer is willing to publicly disclose the reasons for regulatory action;
- there are no other dosage forms of the drug on the market that would be considered a reasonable alternative;
- there are no other drugs or therapies that would be considered to be reasonable alternatives;
- a clinical trial is inappropriate under the circumstances for gathering new or confirmatory evidence of the safety and efficacy of the drug.

4.3.3 Drug shortages and discontinued drugs

In circumstances where a drug is in short supply or is discontinued from the market, the SAP will consider authorizing access to an alternative source of an otherwise marketed drug in circumstances where:

- the drug is considered to be medically necessary for the treatment, diagnosis or prevention of a serious or life-threatening condition;
- the manufacturer is willing to disclose the reasons for the shortage or

discontinuance of the drug;
- there are no other dosage forms of the drug on the market that would be considered a reasonable alternative;
- there are no other drugs or therapies that would be considered to be reasonable alternatives; and
- in the case of a drug shortage, the manufacturer demonstrates that extraordinary efforts have been made to avoid and manage the shortage such as inventory control, rationing etc.

4.4 Processing of the SAR

Following consideration of the SAR, the SAP will either authorize or deny the request. Authorized requests are sent by facsimile to the manufacturer and copied to the practitioner.

SARs that are denied are returned promptly by fax to the practitioner with explanation. The SAP may also contact the practitioner by telephone to discuss the reasons for denial and the procedures for submitting a request with additional information.

5 HOURS OF OPERATION

The SAP operates 24 hours a day, 365 days a year. Regular business hours are weekdays from 8:30 am to 4:30 pm Eastern Standard Time. Outside of regular business hours and during statutory holidays[7], an On Call service is available.

6 REPORTING AND RECORD KEEPING

6.1 What to report

Practitioners agree to report to the manufacturer and to the SAP on the use of a drug and any adverse drug reactions (ADRs) encountered. The use of a drug should also be reported by practitioners using the "Patient Follow-Up Report" form found on the Health Canada website. Reporting should be on a patient by patient basis.

7 New Year's Day -January 1; Good Friday - Friday before Easter Sunday; Easter Monday; Victoria Day - Monday on or before May 24; Canada Day -July 1; Civic Holiday - first Monday in August; Labour Day - first Monday in September; Thanksgiving Day - second Monday in October; Remembrance Day - November 11; Christmas Day - December 25; Boxing Day - December 26.

The SAP has adopted the International Conference of Harmonization (ICH) guidelines[8] to be followed for ADR reporting in regards to what should be reported and the associated timeframes. Specifically, the practitioner shall inform the SAP of any serious unexpected adverse drug reaction within 15 days after becoming aware of the information if the reaction is neither fatal nor life threatening and within seven days after becoming aware of the information if it is fatal or life threatening. ADRs should be reported using the Council for International Organizations of Medical Sciences (CIOMS) forms and sent by facsimile to the SAP (please refer to section 3 for contact information).

Reports from use other than through the SAP, both national and international, should not be reported.

6.2 Record Keeping

Consistent with the conduct of clinical trials in Canada, it is recommended that the practitioner maintain all records for a period of 25 years, in a manner that permits rapid retrieval if necessary. At any time the SAP may request that practitioners account for all quantities of drugs received under the auspices of the SAP.

The manufacturer is required to maintain complete and accurate records of all SAP transactions in a manner that permits rapid response to specific requests to verify the distribution of drug supplies to practitioners.

The SAP maintains electronic and paper records of all Letters of Authorization and Denial issued and all paper records of authorized and denied requests. In addition, the SAP keeps electronic records of requests that are returned as incomplete.

6.3 Return of Unused Products

As a general rule, unused supplies of a drug should bereturned to the manufacturer. Indeed some manufacturers require and enforce this policy. However, practitioners may request that unused supplies of a drug be transferred to a new patient by submitting a SAR and indicating the quantity to be transferred.

8 E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (http://www.ich.org/cache/compo/475-272-1.html#E2A)

7 ADVERTISING

In accordance with section 3 of the *Food and Drugs Act* and section C.08.002 of the *Food and Drug Regulations*, advertising of unauthorized drugs accessed through the SAP is strictly prohibited.

APPENDIX A - Definitions

Adverse drug reaction (ADR): as per the *Food and Drug Regulations*, means noxious and unintended response to a drug which occurs with use or testing for the diagnosis, treatment or prevention of a disease or the modification of an organic function.

ADR reports: a summary of the patient's unexpected adverse drug reactions, as defined below, to the drug. For the most part, ADRs are only *suspected* associations, however, a temporal or possible association is sufficient for a report to be made. Reporting an ADR does not imply a causal link, rather it is a precautionary measure.

Biologic(al) drug: A drug listed under Schedule D of the *Food and Drugs Act*.

Drug: as per the *Food and Drugs Act*, includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, (b) restoring, correcting or modifying organic functions in human beings or animals, or (c) disinfection in premises in which food is manufactured, prepared or kept.

Serious/Life-Threatening: In defining whether a condition is 'serious', Health Canada believes that a matter of discretionary judgement is required. Factors such as survival, day-to-day functioning or the likelihood that the disease if left untreated, will progress from a less severe condition to a more serious one are all taken into account. The latter includes, but is not limited to: acquired immunodeficiency syndrome (AIDS); all other stages of human immunodeficiency virus (HIV) infection; Alzheimer's dementia; Amyotrophic Lateral Sclerosis (ALS); Angina Pectoris; Heart Failure; Cancer; and other diseases that are clearly serious in their full manifestations. 'Serious' conditions are generally associated with morbidity with a substantial impact on day-to-day functioning.

Notice of Compliance (NOC): a notification, issued pursuant to paragraph C.08.004(1)(a) or C.08.004(3)(a), indicating that a manufacturer has complied with sections C.08.002 or C.08.003 and C.08.005.1 of the *Food and Drug Regulations*. Notices of Compliance are issued to a manufacturer following the satisfactory review of a submission.

Notice of Deficiency (NOD): If deficiencies and/or significant omissions that preclude continuing the review are identified during the review of a submission, a NOD will be issued.

Notice of Deficiency - Withdrawal (NOD/W): When the response to a NOD is received, a new Screening 1 period (with an associated performance target) begins. If during the screening process, the response to a NOD is found to contain unsolicited information, is incomplete or deficient, the response to the NOD will be rejected and the submission will be considered withdrawn without prejudice to a refiling. A NOD-Withdrawal Letter will be issued by Health Canada.

Notice of Non-compliance (NON): After the comprehensive review of a submission is complete, a NON will be issued if the submission is deficient or incomplete in complying with the requirements outlined in the *Food and Drugs Act and Regulations*.

Notice of Non-compliance - Withdrawal (NON/W): When the response to a NON is received, a Screening 2 period begins (with an associated performance target). If during the screening process, the response to a NON is found to contain unsolicited information, is incomplete or deficient, the response to the NON will be rejected and the submission will be considered withdrawn without prejudice to a refiling. A NON-Withdrawal Letter will be issued by the responsible Health Canada Directorate.

Practitioner: as per the *Food and Drug Regulations*, a person who is entitled under the laws of a province to treat patients with a prescription drug and is practising their profession in that province.

Serious adverse drug reaction: as per the *Food and Drug Regulations*, noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life threatening or results in death.

Serious unexpected adverse reaction: as per the *Food and Drug Regulations*, a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out in the investigator's brochure or on the label of the drug.

Special Access Request (SAR) form: a standard form used by the SAP to facilitate the request procedure. Practitioners fill out the SAR with the necessary information and submit it to the SAP.