



# CSPS NEWS

THE NEWSLETTER OF THE CANADIAN SOCIETY OF PLASTIC SURGEONS

Vol. 22, No. 1

Spring 2011

## Dr. Dale Birdsell and Dr. Lloyd Carlsen receive 2011 CSPS Lifetime Achievement Award



*Dale Birdsell,  
MD, FRCSC*

Dr. Dale C. Birdsell is a 1961 graduate of the University of Alberta and a member of the CSPS since 1969. He received his postgraduate training in general and plastic surgery at the University of Toronto, and spent a year in research with W. K. Lindsay at the Hospital for Sick Children. Afterwards he studied at Johns Hopkins and Stanford Universities. He returned to Calgary to take up an appointment at the Foothills Hospital where he is currently Clinical Professor of Surgery in the Division of Plastic Surgery. Dr. Birdsell has also served as

chief of the division of plastic surgery and director of the burn unit as well as director of the postgraduate training program in plastic surgery there.

Dale Birdsell is a member of numerous international organizations. He is Fellow of the American College of Surgeons, an honorary member of The Association of Plastic and Reconstructive Surgeons of

*Please see Dr. Birdsell, page 2*

Dr. Lloyd N. Carlsen graduated from Queen's University in 1957. He received postgraduate training in Vancouver, and in Glasgow and Mount Vernon in the United Kingdom as well as in New York City. He joined the staff of Scarborough General Hospital in 1964 and was

chief of plastic surgery there from 1966 to 1999. Dr. Carlsen also served as surgeon-in-chief of the hospital from 1975 - 1978.

Dr. Carlsen established Canada's first burn unit at The Scarborough Hospital (then named Scarborough General Hospital) and went on to build the largest hospital based plastic surgery unit in Canada.

Initially primarily interested in reconstructive surgery of the hand, over the years his main interest shifted to cosmetic surgery. He has been extremely ac-

*Please see Dr. Carlsen, page 2*



*Lloyd Carlsen,  
MD, FRCSC*

A Vision Statement from Drs. Ed Buchel, Danny Peters, Doug McKay, Peter Wyshynski, John Taylor and Don Lalonde

## Canadian Journal of Plastic Surgery at a crossroads

THE CANADIAN JOURNAL OF PLASTIC SURGERY is at a crossroads. The members of the CSPS will be asked to vote on the future of the journal at the CSPS business meeting at 4pm on Sunday May 22 in Vancouver. Currently the journal is owned by Pulsus (Mr Bob Kalina). With negotiations spearheaded by the CSPS board, there is now an opportunity for the CSPS to purchase and own the Canadian Journal of Plastic Surgery for the

first time in its 18 year history. We, the below signed, feel that this is a good option for Canadian Plastic Surgery, for the CSPS, and for the Canadian Journal of Plastic Surgery. We have worked very hard to create a profitable business model, and to set the stage for our Canadian journal to become a serious force in Plastic Surgery. Canadian Plastic Surgery has always been very strong. We feel it is time that we get our Canadian

journal fully indexed and reflect the strength that we have on the international stage with our journal. We have a good plan, and will ask for your support for this plan in Vancouver.

If you agree to this plan, the direction will be as follows:

As of June 1<sup>st</sup>, the Editorship would change.

*Please see page 2, Vision*

## Vision, from page 1

1) Dr Peter Wyshynski and Dr John Taylor would become editors emeritus of CJPS.

2) After careful consideration and deliberation of vision statements by applicants, Dr Ed Buchel (Winnipeg) would become the Editor in Chief, and Dr. Danny Peters (Ottawa) and Dr. Doug McKay (Kingston) would become associate editors. The Board and Reviewers of the Journal would also undergo evolution during the following several months under the direction of the editors

These changes would usher in a new phase in the evolution of the Canadian Journal of Plastic Surgery. Ownership by the Canadian Society of Plastic Surgeons creates a journal that now more than ever would become the voice of our members. This fundamental change to member ownership carries with it the responsibility of all members to participate fully in the production of a world class journal. Changes would not occur overnight, but we believe they are totally possible with your support.

Firstly, the journal would immediately focus on increasing relevance to residents and staff. Practice "RCPSC Exam" type questions and model answers would have a dedicated section in each journal. Papers related to the business of Plastic Surgery and practice management would also be incorporated into every issue. These two features alone would make the CJPS a "must read" feature for the residents right off the bat, as well as helpful to the practicing Canadian surgeon.

Review articles and Canadian consensus opinion papers would form a section of each journal. CME credit would become incorporated. Original articles pertaining to Plastic Surgery, care delivery, public health, and surgical education papers would be encouraged. These would increase international interest and help us achieve the goal of increasing full indexing from our current position of being indexed on Pub Med Central.

While the content is always the most important focus, accessibility to this new information is nearly as important. In this regard, an online presence would be enhanced with Apps (blackberry and iPad and iPhone), Social media (facebook and twitter). Submission of articles and all content would be done through an online submission process that allows not only text and pictures but audio and video inclusion. The online submission process and editorial services will be available as of June 1<sup>st</sup> 2011 to facilitate author participation. Very exciting is the creation of an editorial service direct from Pulsus. This will allow an author to enlist the help of this service to prepare the

original article for publication to the Canadian journal or any other journal of the author's choice for authors who are "technologically or language challenged" for a modest fee.

The Journal would continue to be published quarterly, but it would quadruple in size starting with the summer 2011 edition. The fall 2011 Edition of the Canadian Journal of Plastic Surgery would become the first edition to fully represent the new direction of the Journal.

We believe that we have a good business plan which would allow the Canadian Journal of Plastic Surgery to be purchased from Pulsus with their permission and good will at a very reasonable price, and for a very modest increase in the CSPS member fees. We have met with Pulsus and they are on board and excited about the transition, as well as keen to help us achieve our goals.

We believe that these changes would encourage Canadian members to submit work that represents the quality and diversity of Canadian plastic surgery in our own Canadian journal instead of abroad. The editors and board are excited to be part of the creating a journal that will be a great educational tool for all Canadian plastic surgeons and contribute to a growing knowledge base in plastic surgical care. We hope to get the support of the membership in Vancouver to permit the Canadian Journal of Plastic Surgery to prosper as it should.

## Dr. Birdsell, from page 1

South Africa. In 1994 he received the James Barrett Brown from the American Association of Plastic Surgeons. In 2004, Dr. Birdsell was given the Alberta Medical Association's Medal for Distinguished Service. The AMA noted "Dr. Dale C. Birdsell [...] has devoted his career to promoting the advancement of the science and art of plastic surgery. He has been an example and mentor for plastic surgeons in both Canada and abroad, and for medical residents and medical students. His leadership role among the plastic surgeons of Calgary has advanced the profile of plastic surgery, while his countless hours of lecturing and instructing the general public on the scope and importance of plastic surgery have been an unparalleled success."

Dr. Birdsell founded the Foothills Hospital Burn Unit in 1974 and directed the unit until 1988. He was founder and director of the Calgary plastic surgery residency program from 1976 to 1992 and founder and

director of the Foothills Hospital Hand Clinic from 1976 to 1980.

This busy career has not kept Dr. Birdsell from being actively involved in the societies of which he is a member. He has held numerous positions on the Boards of the Northwest Society of Plastic Surgeons, the Canadian Society of Plastic Surgeons and the Canadian Society for Aesthetic (Cosmetic) Plastic Surgery, serving as President of the CSPS in 1984-85 and of the CSACPS in 1985-86.

In 2009 Dr. Birdsell was honored by the University of Calgary with the establishment of the Dale Birdsell Lecture.

## Dr. Carlsen, from page 1

tive in this field and in 1971 established the Cosmetic Surgery Hospital in Woodbridge, Ontario. Dr. Carlsen served as a volunteer surgeon in Vietnam in 1970 and 1973 and earned a citation from the Minister of Health of Vietnam for his work.

Among his many accomplishments, Dr. Carlsen performed the world's first calf augmentation for a post-polio leg reconstruction and pioneered the use of porcine dressing for burn patients. Dr. Carlsen is a founding member of The Canadian Society for Aesthetic (Cosmetic) Plastic Surgery started in 1972. He also established the Canadian Association for Accreditation of Ambulatory Care Facilities in 1984 out of concern that surgical facilities should meet standards and criteria when operations are performed outside of a general hospital.

A CSPS member since 1965, Dr. Carlsen's memberships also include, to name but a few, American Burn Association, American College of Surgeons, The American Association for Hand Surgery, The American Society of Aesthetic Plastic Surgery, American Society of Plastic and Reconstructive Surgeons, British Association of Plastic

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Surgeons.

Perhaps one of Dr. Carlsen's greatest joys is the training of over 50 young plastic surgeons in his fellowship program throughout his career. Apart from his accomplishments as a surgeon, Dr. Carlsen is an avid mountain skier and scuba diver and had the honour of being on the first "ill fated" Mount Everest expedition in the 70's.

#### Award Presentation

The CSPS Lifetime Achievement Award will be presented to Dr. Birdsell and Dr. Carlsen at the Society's Annual Meeting in Vancouver, British Columbia during the President's Banquet on Sunday evening, May 22nd at the Fairmont Waterfront Hotel.

### Second Annual Evidence-Based Surgery Workshop for Plastic Surgeons, McMaster University

**Program Chair:** Achilleas Thoma, MD, MSc, FRCSC, FACS

**When:** November 3-4, 2011

**Where:** Waterfront Hotel, Burlington, ON

**Registration Fee:** \$500

The Surgical Outcomes Research Centre (SOURCE) at McMaster University is holding its Second Annual Evidence-Based Surgery (EBS) Workshop for Plastic Surgeons on November 3-4, 2011. This 2-day workshop teaches the principles of EBS to plastic surgeons in an interactive, small-group setting, offering one-on-one interaction with experts in surgical research methodology. Each topic is centered on a particular clinical problem leading the group to develop a literature search strategy, identify a relevant article and appraise the paper for validity and applicability to their clinical practice. Topics to be covered will include (1) how to conduct an effective search strategy, (2) how to evaluate a randomized controlled trial, (3) how to evaluate power and sample size, and (4) how to evaluate a study on quality of life. Registration will be limited to 40 participants on a first come, first serve basis.

This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada, approved by McMaster University Continuing Health Sciences Education Program.

To register, please contact: Teegan Ignacy, SOURCE Program Coordinator at ignacyta@mcmaster.ca or 905.522.1155 Ext. 35874.

*Contributed by Don Lalonde, MD, FRCSC (Saint John, NB)*

## Notes on Health Canada Special Access Program Application for authorization to use leeches

SINCE THE fall of 2010, all legal Canadian leech purchases need to be authorized by Health Canada's Special Access Program (SAP). You (the doctor) must fill out a form from Health Canada whether you order leeches on an emergency basis or on an elective basis in case of emergency. The purpose of these notes is to help in filling out the form. On the next page you **will** find a properly filled out application with all of the information needed by Health Canada. You will still need to fill out Section A (your demographics), how many leeches you want in section C (we put in 60 which you can change), and section E where you sign the form and put in your license number as a doctor. You then send the document by fax to 613.941.2108 or email to [sapdrugs@hc-sc.gc.ca](mailto:sapdrugs@hc-sc.gc.ca).

Health Canada will call, email, or fax the authorization to purchase the leeches to you, and you can purchase leeches from LeechesUSA.

More detailed notes on how to fill out the form from Health Canada are included at the bottom of form B: Future Use Request on the Health Canada Website.

You do not need to fill out patient initials if this is the first time you are getting approval for leeches from Health Canada, but you do if it is the second time you are getting their approval (see below).

#### Ordering leeches electively

We recommend that all hospitals where leeches may be needed on an emergency basis keep a stock on hand to avoid delays should they be required, and you may consider ordering them before you have an emergency. You can go online to Health Canada Special Access Program at "[http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf2\\_pasf2-eng.php2](http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf2_pasf2-eng.php2)" and download an empty form B Future Use Request, to fill it out, or you can use the one we are providing you here. Send in the filled out form and Health Canada will authorize the leeches. Call 613.941.2108 for help.

#### Ordering leeches as an emergency

Should you require leeches as an emergency, Health Canada officials are available 24 hours a day, 365 days a year to remove any road blocks you may encounter at 613.941.2108 **and then press 0. It is important that you do not listen to the menu and leave a message. You must just press 0 to get to the human and avoid delays.**

**Is this the first time or the second**

**time you are getting authorization for leeches from Health Canada?** If this is the first time you are getting special access from Health Canada's Special Access Program, you are not required to fill out the patient initials. Just ignore this part as we have ticked off "Yes" in the first future use box. However, you **do** need to fill out the patient initials on the **second** request from Health Canada. They want to know who you gave leeches to with your previous batch approved by them. You need to keep track of these from now on until Leeches USA gets market approval. Once they get market approval, you can go back to ordering leeches from them as before.

On your second request to the Health Canada Special Access Program, you will need to click the "No" box, and you will need to fill out the initials of patients you treated with the leeches obtained from your first request:

1<sup>ST</sup> FUTURE USE REQUEST: YES NO.



The IPRAS 2011 Vancouver Organizing Committee looks forward to welcoming you to Vancouver from May 22-27

Dr. Ronald M. Zuker, FRCSC  
Chair, IPRAS 2011

Dr. Jean-Paul Bossé, FRCSC  
Honorary Chair, IPRAS 2011

Dr. Peter C. Neligan, FRCSC  
Chair, Scientific Program  
Committee

Dr. Donald H. Lalonde, FRCSC  
Chair, Organizing Committee

Dr. Gordon H. Wilkes, FRCSC  
Chair, Finance & Sponsorship  
Committee

Dr. Richard Warren, FRCSC,  
Chair, Local Host Committee

Ms. Karyn Wagner  
Organizing Committee Coordinator  
Executive Director, Canadian  
Society of Plastic Surgeons



**SPECIAL ACCESS PROGRAMME  
FORM B – FUTURE USE REQUEST**

SECTION A: PRACTITIONER INFORMATION		
Practitioner's Name:		
Hospital or Clinic Name: (if applicable)		
Address: (shipping address only)		
City:	Province:	Postal Code:
Contact Person: (if other than practitioner)		Send Drug c/o:
Contact Telephone #:		In-patient Hospital Pharmacy <input type="checkbox"/>
Contact Fax #:		Practitioner's Office <input type="checkbox"/>
		Nuclear Medicine <input type="checkbox"/>
		Blood Bank <input type="checkbox"/>
Contact's Email Address: (optional)	Practitioner's Email Address: (optional)	

SECTION B: DRUG AND MANUFACTURER INFORMATION	
Trade Name:	Other Name:
Manufacturer:	PO#:
Route of Administration: ORAL <input type="checkbox"/> I.V. <input type="checkbox"/> I.M. <input type="checkbox"/> TOPICAL <input type="checkbox"/> S.C. <input type="checkbox"/> OTHER:	
Dosage Form: TAB <input type="checkbox"/> CAP <input type="checkbox"/> LIQUID <input type="checkbox"/> POWDER <input type="checkbox"/> CREAM <input type="checkbox"/> OINT. <input type="checkbox"/> PATCH <input type="checkbox"/> OTHER:	

SECTION C: PATIENT-PRODUCT TRACKING INFORMATION		
INDICATION _____	STRENGTH _____	QUANTITY _____ (I.E. SPECIFIC NUMBER OF VIALS/TABS)
1 <sup>ST</sup> FUTURE USE REQUEST: YES <input type="checkbox"/> NO <input type="checkbox"/>		
<b>If NO,</b>		
1. PLEASE PROVIDE A LIST OF PATIENTS WHO RECEIVED THE PREVIOUS SUPPLY IN THE TABLE BELOW.		
2. IF REPLACING EXPIRED STOCK PLEASE CHECK HERE <input type="checkbox"/>		

PATIENT INITIALS (E.G. A.B.C.)	DOB (DD/MM/YYYY)	GENDER	INDICATION FOR USE OF DRUG	NEW OR REPEAT PATIENT VIA THE SAP FOR THIS DRUG?	QUANTITY RELEASED (E.G. ## TABS)	DATE ADMINISTERED (DD/MM/YY)
		M <input type="checkbox"/> F <input type="checkbox"/>		N <input type="checkbox"/> R <input type="checkbox"/>		
		M <input type="checkbox"/> F <input type="checkbox"/>		N <input type="checkbox"/> R <input type="checkbox"/>		
		M <input type="checkbox"/> F <input type="checkbox"/>		N <input type="checkbox"/> R <input type="checkbox"/>		





**SECTION D: CLINICAL RATIONALE**

1a) Please specify the circumstances in which the drug will be used including information on conventional therapies considered, failed or that are unavailable to achieve an adequate response. Explain why this product is needed on a future use basis.

b) What specifically about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s)? Please explain.

2) Please provide **specific** data, references and/or resources in your possession, with respect to the use safety and efficacy that support your decision to prescribe this drug. For citations please include journal/article titles, author(s), volume, issue, date and page information. Check here if reference(s) is/are attached

**SECTION E: PRACTITIONER ATTESTATION**

I, the practitioner, am accessing this non-marketed drug for use in the emergency treatment of a patient under my care in accordance with the *Food and Drug Regulations* C.08.010.

I, the practitioner, am aware that by accessing this drug through the SAP, the sale of the drug is exempt from all aspects of the *Food and Drugs Regulations* including those respecting the safety, efficacy and quality.

I, the practitioner, agree to provide a report on the results of the use of the drug including information on Adverse Drug Reactions and, on request, to account for quantities of the drug received.

Practitioner's Signature:

License #:

Date:

Special Access Programme  
Therapeutic Products Directorate  
c/o Health Canada  
AL 3105 A  
Tunney's Pasture  
Ottawa, ON K1A 0K9

**FAX all requests to (613) 941-3194**  
For urgent requests requiring immediate attention please follow up with a call to the SAP at:  
**(613) 941-2108**

**AUTHORIZATION ONLY VALID WITH SIGNATURE & SAP STAMP**

**website:** [http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index_e.html)

**email:** [sapdrugs@hc-sc.gc.ca](mailto:sapdrugs@hc-sc.gc.ca)

# Health Canada's Special Access Programme (SAP)

## Instructions for Making a Special Access Future Use Request

### FORM B

Future use requests are made in circumstances where non-marketed drugs are required in anticipation of patients faced with a medical emergency. The practitioner should include a rationale as to why the drug is required on hand as opposed to requesting it on a patient specific basis.

## Background on the Special Access Programme

The SAP considers requests from practitioners for access to non-marketed 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, and/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. This authority however, does not extend to covering the cost of drugs and does not take into consideration the cost of marketed alternatives. If access is granted, the physician agrees to report on the use of the drug including any adverse events encountered with such use, and must account for all quantities received to both the SAP and the manufacturer.

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.

The SAP does not authorize the use or administration of a drug. This authority falls within the practice of medicine, which is regulated at the provincial level. A 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 of the manufacturer respecting safety, efficacy and quality. 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. The SAP strongly encourages practitioners treating individuals with drugs obtained through the SAP to seek informed consent before treatment.

Practitioners are encouraged to contact individual manufacturers to confirm the availability of a drug as well as to obtain the most up-to-date drug information such as prescribing information and other data supporting the use of the drug. In all cases, the manufacturer has the final word on whether the drug will be supplied. The manufacturer also 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 drug released, request further patient information, restrict the indications for which it is released, etc. Inquiries concerning the shipping, cost and/or payment should be directed to the manufacturer of the drug.

Please refer to the SAP guidance document for further information.

## Instructions for completing the Special Access Request Form

The request form consists of two pages containing five sections. Practitioners are required to complete all five sections of the form each time a request is made, including renewal requests. The five sections are as follows:

### SECTION A: PRACTITIONER AND SHIPPING INFORMATION

**Practitioner's Name:** First and last name of the requesting practitioner.

**Note:** Practitioner is defined as a person authorized by law of a province of Canada to treat patients with any drug listed or described in Schedule F of the Regulations as a drug substance intended for human use and requiring a prescription to be sold in Canada.

**Hospital or Clinic Name:** Full name of clinic or hospital where drug is to be sent- if applicable.

**Address:** Full name and address of the practitioner's office/clinic or hospital pharmacy where the drug is to be delivered, including the city, province and postal code.

**Contact Person:** Full name and position (e.g. Pharmacist, Nurse, Resident, etc.) of the person completing the form, if other than the requesting practitioner

**Contact Tel. # /Fax#:** A telephone and fax number including an area code and extension (if applicable) where the practitioner or contact person can be reached if further information or follow-up is required.

**Send Drug c/o:** Check the box that applies to where the drug is to be sent: a hospital in-patient pharmacy, the practitioner's office, a nuclear medicine department or blood bank

**Note:** A drug cannot be sent to retail or out-patient pharmacy.

**Contact's email address:** An email address for the contact person should they need to be reached if further information or follow-up is required. This is an optional field.

**Practitioner's email address:** An email address for the requesting practitioner should they need to be reached if further information or follow-up is required. This is an optional field.

## SECTION B: DRUG AND MANUFACTURER INFORMATION

**Trade Name/Other Name:** Full name of drug, including when possible, both trade and generic name or company designated code.

**Name of Manufacturer:** Full name of the manufacturer and location if applicable (i.e. Canadian office.) **Note:** For new drugs if the requesting practitioner has spoken to a representative at the company regarding their request, please provide a note indicating this including a name and number for the contact person.

**PO#:** An optional field that can be used by hospitals or other institutions to specify a purchase order number

**Route of Administration/Dosage Form:** Check the boxes that apply, or specify "other" if applicable.

## SECTION C: PATIENT-PRODUCT TRACKING INFORMATION.

**Indication:** The indication for which the drug is anticipated to be used for.

**Strength:** Required strength or combination of strengths.

**Quantity:** Precise number of tabs, vials, etc. requested to keep on hand.

**1<sup>st</sup> future use request:**

If YES, then proceed to the clinical rationale section of the request form- Section D.

If NO,

1) then the requesting practitioner has had a previous future use request authorized for this product. In order for the SAP to consider another request, the practitioner will need to provide a list of patients on whom the previous supply authorized was used. This information is to be provided in the table found in section C. If additional fields are required, extra copies of page 2 of the form should be attached.

Or

2) If drug has expired prior to being used, please check off the corresponding box.

**Initials:** First, middle (if applicable) and last initials of the patient.

**Note:** To ensure the patient's confidentiality, please do not indicate the patient's full name.

**DOB:** Specify the date of birth in order of date, month, year order (i.e. DD/MM/YYYY).

**Sex:** Check off the applicable box for the specified patient- Male or Female.

**Indication:** Exact medical indication for which the drug is being requested for.

**New or Repeat Patient:** Check the applicable box indicating whether this represents an initial (i.e. new) treatment or a repeat treatment for the patient for the specified drug via the SAP.

**Quantity Released:** Specify the amount of drug released for each patient. (i.e. # tabs, vials, bottles).

**Date Administered:** Specify the date the drug was administered to the identified patient in the format date, month and year (i.e. DD/MM/YY).



**SECTION D: CLINICAL RATIONALE****Question 1a):**

Specify the circumstances in which the drug will be used or is being requested for including, information on conventional therapies considered, failed or that are unavailable to achieve an adequate response. Explain with details why this drug is being requested as a future use supply.

**Question 1b):**

With details, explain what about this drug (e.g. mechanism of action, drug class, dosage form) makes it the best choice for your patient(s).

**Question 2) References:**

Provide **specific** data/references with respect to the safety and efficacy of the product that support the requesting practitioner's decision to prescribe the drug for the specified indication. This can be in the form of medical literature, clinical protocols, investigator brochures etc. If copies of the reference(s) are appended to the request form, please check off the box. Otherwise provide a complete citation including journal/article titles, author(s), volume, issue, date and page information.

**SECTION E: PRACTITIONER ATTESTATION**

Section E consists of three attestations for the requesting practitioner to acknowledge and sign off on before requesting a non-marketed drug through the SAP.

**Practitioner's Signature:** Requesting practitioner's signature.

**License #:** Requesting practitioner's licence # (i.e. license to practice medicine or dentistry as issued by a provincial licensing authority).

**Date:** Date when request was signed and submitted to the SAP.

## Processing of Requests and Hours of Operation

Completed forms should be faxed to the SAP without an accompanying cover sheet. Telephone calls should be reserved for urgent requests requiring immediate attention.

A complete form does not guarantee that a request will be authorized and additional information may be required during the consideration process. Every effort is made to process requests within 24 hours of receipt. However, given the mandate of the Programme and the volume of requests received, the SAP adopts a triage system to ensure that requests for drugs for life-threatening conditions take precedence over less urgent requests. 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 drugs.

After consideration of a request, an authorization may be granted. The manufacturer is notified by fax. A Letter of Authorization is sent to the manufacturer and copied to the practitioner. Practitioners will be notified in the event that a request is denied.

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, an on-call officer is available. The on-call officer can be reached by calling the regular business line, (613) 941-2108 and pressing 0. The officer will either answer directly or return the phone call within 20 minutes. Should an authorization be provided, practitioners will be required to submit a completed request form to the SAP, by fax, the following day.