INTERIM GUIDANCE DOCUMENT

Therapeutic Products Programme

CONTENTS

Exemption under Section 56 for Medical Purposes

1. PURPOSE OR OBJECTIVE

To provide guidance for an application for exemption under Section 56 of the *Controlled Drugs and Substances Act* (*CDSA*) for medical purposes.

2. BACKGROUND

Regulation of Controlled Drugs/Substances in Canada

Health Canada is a national and international partner in the management of controlled drugs and substances through the administration of the *CDSA* and its regulations. Canada is also a signatory to the following international treaties: the *Single Convention on Narcotic Drugs, 1961*, as amended by the 1972 Protocol, the 1971 *Convention on Psychotropic Substances*, and the 1988 *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*.

By enacting the CDSA, Parliament has prohibited certain activities in relation to substances that are included in the schedules to the Act. The Regulations made under the CDSA

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authorize these activities to be done by specified individuals in the manner described in the Regulations. Pursuant to section 56 of the CDSA (hereinafter referred to as Section 56), Parliament has also given the Minister of Health (hereinafter the "Minister") discretionary power to grant exemptions from all or any of the provisions of the CDSA or its regulations in exceptional circumstances. Such an exemption, subject to any terms and conditions deemed necessary, could permit an activity that is otherwise prohibited under the CDSA.

Section 56 states that the Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons or any controlled substance or precursor or any class thereof from the application of all or any of the provisions of this Act or the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

3. SCOPE

This document is meant to provide guidance to individuals in making applications to the Minister for an exemption for a medical purpose under Section 56.

This is a guidance document only. It is meant to clarify the broad terminology contained in Section 56 and to explain the process of application for and review of a request for an exemption under that section.

By its very nature, a Section 56 exemption may be granted only in exceptional circumstances.

The Minister may grant an exemption for a medical purpose under Section 56 if, among other things, in the opinion of the Minister, the exemption is necessary for that medical purpose.

Exemptions under Section 56 are limited to drugs/substances and activities subject to the CDSA and its regulations.

Exemptions under Section 56 are not a mechanism to promote or encourage the use of drugs/substances for which approval for general marketing in Canada has not been granted or to circumvent other conventional avenues of access.

4. INTERPRETATION

4.1 Meaning of "Practitioner":

In this document, the term "practitioner" has the same meaning as in subsection 2(1) of

the CDSA. It means a person who is registered and entitled under the laws of a province to practice in that province the profession of medicine, dentistry or veterinary medicine.

4.2 Meaning of "necessary for a medical purpose":

Pursuant to Section 56, the Minister may grant an exemption if, in the opinion of the Minister, the exemption is necessary for a medical purpose. In determining whether an exemption is necessary for a medical purpose in a particular case, the Minister may consider certain factors, such as:

- the nature and seriousness of the medical condition of the patient who will be treated with the controlled drug/substance for which an exemption is sought (including whether the life of the patient would be threatened if the use of the drug/substance were not employed as a treatment for the patient's condition);

- whether, in the particular case, the benefits of employing such treatment for the patient outweigh the risks;

- whether all therapies currently available in Canada have been reasonably tried but have failed or in cases where therapies have not been tried, such therapies have been reasonably considered and been found to be inappropriate by the treating practitioner;

- whether all other means of lawful access, such as access in the context of research activities, including clinical trials, to which the patient could reasonably be expected to participate, have been exhausted;

- whether the patient's treating practitioner is also of the opinion that access to the controlled drug/substance, in the manner and form requested for the patient, is necessary for a medical purpose.

5. RESPONSIBILITIES AND PROCEDURES

5.1 Application

5.1.1 The application for exemption under Section 56 should be submitted in

writing, and specify the activity for which the exemption is sought and contain the following information:

A. Practitioner information:
   - i full name;
   - ii licence number issued by the relevant professional provincial licencing authority ;
   - iii specialty, if applicable;
   - iv mailing address of practitioner's office/clinic or hospital;
   - v telephone number;

B. Patient information:
   - i full name;
   - ii address, city, province , postal code and telephone number;
   - iii date of birth;
   - iv gender;
   - v medical diagnosis provided by the practitioner;

C. Controlled drug/substance information:
   - i name of drug/substance;
   - ii name and address of the fabricator or distributor who is licensed under *CDSA*, the *Narcotic Control Regulations* and the *Food and Drug Regulations* and who has the capacity to fabricate and distribute in accordance with international drug treaties, if applicable;
   - iii dosage form, concentration of the medicinal ingredient(s) and route of administration;
   - iv medical indication for the use of the controlled drug/substance;
   - v intended single and daily dosage;
   - vi quantity of drug/substance requested;

D. A statement from the practitioner stating that, in his or her opinion, access to the controlled drug/substance for which the exemption is sought, in the manner and form requested, is necessary for a medical purpose. The practitioner should also provide the following details:

   - i reasons why the controlled drug/substance is necessary for a medical purpose;
   - ii risks and benefits associated with the controlled drug/substance;
   - iii all therapies that have been reasonably tried and explanation for their failure;

iv all therapies that have not been tried but have been reasonably considered and explanation as to why they were deemed inappropriate;

v pertinent information (eg. findings on physical examination, laboratory findings) upon which medical diagnosis (B.v) was established;

vi proposed treatment protocol including all interventions.

5.1.2 The Minister may request additional information specific to the case .

5.1.3 Where any information specified in section 5.1.1 or requested by the Minister pursuant to 5.1.2 cannot be provided, the reasons should be stated.

5.1.4 Address

Applications should be sent to the following address:

Controlled Substances Division
Bureau of Drug Surveillance
Therapeutic Products Programme
Health Canada
Finance Building, AL # 0201D4
Tunney's Pasture
K1A 1B9

The application should stipulate the parts thereof that should not be disclosed pursuant to the *Access to Information Act*, in particular, pursuant to section 19 and 20 of that *Act*, the reason why those parts should not be disclosed and the period during which those parts should remain undisclosed. The application should also stipulate the parts thereof for which there is no objection to disclosure pursuant to the *Access to Information Act*.

5.2 Receipt of Application

5.2.1 Upon receipt of an application, an acknowledgment of receipt will be sent to the Applicant within 10 business days.

5.3. Review of Application

5.3.1 The Minister will review applications on a case by case basis and will

determine, among other things, whether the exemption is necessary for a medical purpose (see section 4.2, above).

In deciding whether to grant the exemption, the Minister may also consider other factors, such as:

i the risks associated with granting the exemption in the specific case, such as:
   a. the health and safety hazards associated with the controlled drug/substance and related activities;
   b. the potential for diversion

ii whether terms and conditions can adequately address these risks; and

iii other concerns that may be specific to the case.

5.3.2 To the extent that the Minister may rely on evidence that has not previously been seen by the Applicant, such evidence will be provided to the Applicant, and the Applicant will be given an opportunity to respond before a decision is made.

5.4 Outcome of Review

5.4.1 Granting of Exemption

i any letter granting an exemption shall specify the provision(s) of the *CDSA* or its regulations from which the Applicant (and others if necessary) is exempt;

ii the exemption shall be subject to the terms and conditions that the Minister deems necessary;

iii all other applicable requirements of the *Food and Drugs Act* and its regulations, the *CDSA* and its regulations, and other applicable laws and statutes of Canada will continue to apply ;

iv an exemption from all or any of the provisions of the *CDSA* and its regulations does not constitute an opinion from Health Canada on the safety, effectiveness and quality within the meaning given to those words under the *Food and Drugs Act* and the *Food and Drug Regulations*.

5.5 Role of the practitioner in the case where exemption is granted

5.5.1 As part of the terms and conditions, the Minister may require that the practitioner maintain an active role in the treatment of the patient, including reporting periodically to the Bureau of Drug Surveillance on such matters as:

i the progress and/or outcome of the use of the controlled drug/substance;
ii adverse reactions encountered during treatment with the controlled drug/substance.