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June 15, 2001

Le 15 juin, 2001

Notification of passage of Regulations

Please be advised that the following Schedule of Amendments was passed by Order-in-Council and appears in the *Canada Gazette*, *Part II* of:

DATE: July 4, 2001

Controlled Drugs and Substances Act -

Marihuana Medical Access Regulations

Regulations amending the Narcotic Control Regulations

REGISTRATION: SOR 2001-227

P.C.: 1146

PASSAGE : June 14, 2001

Avis d'adoption du Règlement

Veuillez prendre note que l'annexe qui suit a été adoptée par décret et apparaît dans la *Gazette du Canada, Partie II* du:

DATE : Le 4 juillet, 2001

Loi réglementant certaines drogues et autres substances -

Règlement sur l'accès à la marihuana à des fins médicales

Règlement modifiant le Règlement sur les stupéfiants

ENREGISTREMENT : DORS 2001-227

C.P. : 1146

PASSAGE : Le 14 juin, 2001

Bruce Erickson
Policy and Regulatory Affairs Division/Division des politiques et de la règlementation

Attachments

Pièces jointes

JUS-602460

(SOR/DORS)

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Marihuana Medical Access Regulations*.

[a] S.C. 1996, c. 19

JUS-602460

(SOR/DORS)

MARIHUANA MEDICAL ACCESS REGULATIONS

INTERPRETATION

1. (1) The following definitions apply in these Regulations.

"Act" means the *Controlled Drugs and Substances Act*. (*Loi*)

"adverse drug reaction" means a noxious and unintended response to a drug that occurs at doses normally used or tested for the diagnosis, treatment or prevention of a medical condition or the modification of an organic function. (*réaction indésirable à une drogue*)

"authorization to possess" means an authorization to possess dried marihuana issued under section 11. (*autorisation de possession*)

"category 1 symptom" means a symptom that is associated with a terminal illness or its medical treatment. (*symptôme de catégorie 1*)

"category 2 symptom" means a symptom, other than a category 1 symptom, that is set out in column 2 of the schedule and that is associated with a medical condition set out in column 1 or its medical treatment. (*symptôme de catégorie 2*)

"category 3 symptom" means a symptom, other than a category 1 or 2 symptom, that is associated with a medical condition or its medical treatment. (*symptôme de catégorie 3*)

"conventional treatment" means, in respect of a symptom, a medical or surgical treatment that is generally accepted by the Canadian medical community as a treatment for the symptom. (*traitement conventionnel*)

"designated drug offence" means

(*a*) an offence against section 39, 44.2, 44.3, 48, 50.2 or 50.3 of the *Food and Drugs Act*, as those provisions read immediately before May 14, 1997;

(*b*) an offence against section 4, 5, 6, 19.1 or 19.2 of the *Narcotic Control Act,* as those provisions read immediately before May 14, 1997;

(*c*) an offence under Part I of the Act, except subsection 4(1); or

(*d*) a conspiracy or an attempt to commit, being an accessory after the fact in relation to or any counselling in relation to an offence referred to in any of paragraphs (*a*) to (*c*). (*infraction désignée en matière de drogue*)

"designated marihuana offence" means

(*a*) an offence, in respect of marihuana, against section 5 of the Act, or against section 6 of the Act except with respect to importation; or

(*b*) a conspiracy or an attempt to commit or being an accessory after the fact in relation to or any counselling in relation to an offence referred to in paragraph (*a*). (*infraction désignée relativement à la marihuana*)

"designated person" means the person designated, in an application made under section 37, to produce marihuana for the applicant. (*personne désignée*)

"designated-person production licence" means a licence issued under section 40. (*licence de production à titre de personne désignée*)

"dried marihuana" means harvested marihuana that has been subjected to any drying process. (*marihuana séchée*)

"licence to produce" means either a personal-use production licence or a designated-person production licence. (*licence de production*)

"marihuana" means the substance referred to as "Cannabis (marihuana)" in subitem 1(2) of Schedule II to the Act. (*marihuana*)

"medical practitioner" means a person who is authorized under the laws of a province to practise medicine in that province and who is not named in a notice given under section 58 or 59 of the *Narcotic Control Regulations*. (*médecin*)

"medical purpose" means the purpose of mitigating a person's category 1, 2 or 3 symptom identified in an application for an authorization to possess. (*fins médicales*)

"personal-use production licence" means a licence issued under section 29. (*licence de production à des fins personnelles*)

"production area" means the place where the production of marihuana is conducted, that is

(*a*) entirely indoors;

(*b*) entirely outdoors; or

(*c*) partly indoors and partly outdoors but without any overlapping period between the two types of production. (*aire de production*)

"specialist" means a medical practitioner who is recognized as a specialist by the medical licensing authority of the province in which the practitioner is authorized to practise medicine. (*spécialiste*)

"terminal illness" means a medical condition for which the prognosis is death within 12 months. (*maladie en phase terminale*)

(2) For the purpose of sections 28 and 53, a site for the production of marihuana is considered to be adjacent to a place if the boundary of the land on which the site is located has at least one point in common with the boundary of the land on which the place is located.

PART 1

AUTHORIZATION TO POSSESS

Authorized Activity

2. The holder of an authorization to possess is authorized to possess dried marihuana, in accordance with the authorization, for the medical purpose of the holder.

Eligibility for Authorization to Possess

3. A person is eligible to be issued an authorization to possess only if the person is an individual ordinarily resident in Canada.

Application for Authorization to Possess

4. (1) A person seeking an authorization to possess dried marihuana for a medical purpose shall submit an application to the Minister.

(2) An application under subsection (1) shall contain

(*a*) a declaration of the applicant;

(*b*) a medical declaration that is made

(i) in the case of an application based on a category 1 symptom, by the medical practitioner of the applicant, or

(ii) in the case of an application based on a category 2 or 3 symptom, by a specialist;

(*c*) if the application is based on a category 3 symptom, a second medical declaration made by another specialist, that supports the medical declaration made under subparagraph (*b*)(ii); and

(*d*) two copies of a current photograph of the applicant.

Applicant's Declaration

5. (1) The declaration of the applicant under paragraph 4(2)(*a*) must indicate

(*a*) the applicant's name, date of birth and gender;

(*b*) the full address of the place where the applicant ordinarily resides as well as the applicant's telephone number and, if applicable, facsimile transmission number and e-mail address;

(*c*) the mailing address of the place referred to in paragraph (*b*), if different;

(*d*) if the place referred to in paragraph (*b*) is an establishment that is not a private residence, the type and name of the establishment;

(*e*) that the authorization is sought in respect of marihuana either

(i) to be produced by the applicant or a designated person, in which case the designated person must be named, or

(ii) to be obtained under the *Narcotic Control Regulations,* in which case the licensed dealer who produces or imports the marihuana must be named;

(*f*) that the applicant is aware that no notice of compliance has been issued under the *Food and Drugs Act* concerning the safety and effectiveness of marihuana as a drug and that the applicant understands the significance of that fact; and

(*g*) that the applicant has discussed the risks of using marihuana with the medical practitioner providing the medical declaration under paragraph 4(2)(*b*), and consents to using it for the recommended medical purpose.

(2) The declaration must be dated and signed by the applicant attesting that the information contained in it is correct and complete.

Medical Declarations

6. (1) The medical declaration under paragraph 4(2)(*b*) must indicate, in all cases

(*a*) the medical practitioner's or specialist's name, business address and telephone number, provincial medical licence number and, if applicable, facsimile transmission number and e-mail address;

(*b*) the applicant's medical condition, the symptom that is associated with that condition or its treatment and that is the basis for the application and whether the symptom is a category 1, 2 or 3 symptom;

(*c*) the daily dosage of dried marihuana, in grams, and the form and route of administration, recommended for the applicant; and

(*d*) the period for which the use of marihuana is recommended, if less than 12 months.

(2) In the case of a category 1 symptom, the medical declaration must also indicate that

(*a*) the applicant suffers from a terminal illness;

(*b*) all conventional treatments for the symptom have been tried, or have at least been considered;

(*c*) the recommended use of marihuana would mitigate the symptom;

(*d*) the benefits from the applicant's recommended use of marihuana would outweigh any risks associated with that use; and

(*e*) the medical practitioner is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

(3) In the case of a category 2 symptom, the medical declaration must also indicate that

(*a*) the specialist practices in an area of medicine, to be named by the specialist in the declaration, that is relevant to the treatment of the applicant's medical condition;

(*b*) all conventional treatments for the symptom have been tried, or have at least been considered, and that each of them is medically inappropriate because

(i) the treatment was ineffective,

(ii) the applicant has experienced an allergic reaction to the drug used as a treatment, or there is a risk that the applicant would experience cross-sensitivity to a drug of that class,

(iii) the applicant has experienced an adverse drug reaction to the drug used as a treatment, or there is a risk that the applicant would experience an adverse drug reaction based on a previous adverse drug reaction to a drug of the same class,

(iv) the drug used as a treatment has resulted in an undesirable interaction with another medication being used by the applicant, or there is a risk that this would occur,

(v) the drug used as a treatment is contra-indicated, or

(vi) the drug under consideration as a treatment has a similar chemical structure and pharmacological activity to a drug that has been ineffective for the applicant;

(*c*) the recommended use of marihuana would mitigate the symptom;

(*d*) the benefits from the applicant's recommended use of marihuana would outweigh any risks associated with that use, including risks associated with the long-term use of marihuana; and

(*e*) the specialist is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

(4) In the case of a category 3 symptom, the medical declaration must also indicate

(*a*) the matters referred to in subsection (3); and

(*b*) all conventional treatments that have been tried or considered for the symptom and the reasons, from among those mentioned in paragraph (3)(*b*), why the specialist considers that those treatments are medically inappropriate.

7. In the case of a category 3 symptom, the second medical declaration under paragraph 4(2)(*c*) must indicate

(*a*) the specialist's name, business address and telephone number, provincial medical licence number and, if applicable, facsimile transmission number and e-mail address;

(*b*) that the specialist practices in an area of medicine, to be named by the specialist in the declaration, that is relevant to the treatment of the applicant's medical condition;

(*c*) that the specialist is aware that the application is in relation to the mitigation of the symptom identified under paragraph 6(1)(*b*) and that the symptom is associated with the medical condition identified under that paragraph or its treatment;

(*d*) that the specialist has reviewed the applicant's medical file and the information provided under paragraph 6(4)(*b*) and has discussed the applicant's case with the specialist providing that information and agrees with the statements referred to in paragraphs 6(3)(*c*) and (*d*); and

(*e*) that the specialist is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

8. A medical declaration under section 6 or 7 must be dated and signed by the medical practitioner or specialist making it and must attest that the information contained in the declaration is correct and complete.

Dosage In Excess of 5 Grams

9. If the daily dosage recommended under paragraph 6(1)(*c*) is more than five grams, the medical practitioner or specialist providing the medical declaration under paragraph 4(2)(*b*) must also indicate that

(*a*) the risks associated with an elevated daily dosage of marihuana have been considered, including risks with respect to the effect on the applicant's cardio-vascular, pulmonary and immune systems and psychomotor performance, as well as potential drug dependency; and

(*b*) the benefits from the applicant's use of marihuana according to the recommended daily dosage would outweigh the risks associated with that dosage, including risks associated with the long-term use of marihuana.

Photograph

10. The photograph required under paragraph 4(2)(*d*) must clearly identify the applicant and must

(*a*) show a full front-view of the applicant's head and shoulders against a plain contrasting background;

(*b*) have dimensions of at least 43 mm × 54 mm (1 11/16 inches × 2 1/8 inches) and not more than 50 mm × 70 mm (2 inches × 2 3/4 inches), and has a view of the applicant's head that is at least 30 mm (1.375 inches) in length;

(*c*) show the applicant's face unobscured by sunglasses or any other object; and

(*d*) be certified, on the reverse side, by a medical practitioner treating the applicant, to be an accurate representation of the applicant.

Issuance of Authorization to Possess

11. (1) Subject to section 12, if the requirements of sections 4 to 10 are met, the Minister shall issue to the applicant an authorization to possess for the medical purpose mentioned in the application, and shall provide notice of the authorization to the medical practitioner or specialist who made the medical declaration under paragraph 4(2)(*b*).

(2) The authorization shall indicate

(*a*) the name, date of birth and gender of the holder of the authorization;

(*b*) the full address of the place where the holder ordinarily resides;

(*c*) the authorization number;

(*d*) the name and category of the symptom;

(*e*) the medical condition, or its treatment, with which the symptom is associated;

(*f*) the maximum quantity of dried marihuana, in grams, that the holder may possess at any time;

(*g*) the date of issue; and

(*h*) the date of expiry.

(3) The maximum quantity of dried marihuana referred to in paragraph (2)(*f*) or resulting from an amendment under subsection 20(1) or 22(3) is the amount determined according to the following formula:

$$A \times 30$$

where A is the daily dosage of dried marihuana, in grams, recommended for the holder under paragraph 6(1)(*c*), 19(1)(*c*) or 22(2)(*b*), whichever applies.

Grounds for Refusal

12. (1) The Minister shall refuse to issue an authorization to possess if

(*a*) the applicant is not eligible under section 3;

(*b*) any information, statement or other item included in the application is false or misleading;

(*c*) the application involves a category 3 symptom and either all conventional treatments have not been tried or considered or they are considered to be medically inappropriate for any reason not mentioned in paragraph 6(3)(*b*); or

(*d*) the person mentioned in the authorization application as a licensed dealer under the *Narcotic Control Regulations* does not have a valid licence to distribute marihuana under those Regulations.

(2) If the Minister proposes to refuse to issue an authorization to possess, the Minister shall

(*a*) notify the applicant in writing of the reason for the proposed refusal; and

(*b*) give the applicant an opportunity to be heard.

Expiry of Authorization

13. An authorization to possess expires 12 months after its date of issue or, if a shorter period is specified in the application for the authorization under paragraph 6(1)(*d*), at the end of that period.

Renewal of Authorization to Possess

14. (1) An application to renew an authorization to possess shall be made to the Minister by the holder of the authorization and must include

(*a*) the authorization number; and

(*b*) the material required under sections 4 to 10, excluding, in the case of a category 3 symptom, the second medical declaration mentioned in paragraph 4(2)(*c*).

(2) For the purpose of paragraph (1)(*b*), a photograph referred to in paragraph 4(2)(*d*) is required only with every second renewal application.

15. If an authorization to possess for a category 1 symptom has expired and, within 12 months after the expiry, a new application with respect to the category 1 symptom is made by the person who was the holder of the expired authorization, the new application is considered to be an application to renew the expired authorization.

16. An authorization to possess for a category 1 symptom may be renewed only once for that symptom; however, an application for an authorization to possess may be made for that symptom as a category 2 or 3 symptom, whichever applies.

17. Subject to section 18, if an application complies with section 14, the Minister shall renew the authorization to possess for the medical purpose mentioned in the application.

18. The Minister shall refuse to renew an authorization to possess

(*a*) for any reason referred to in section 12; or

(*b*) in the case of an authorization to possess for a category 1 symptom, if the authorization has already been renewed for that symptom.

Amendment of Authorization to Possess

19. (1) An application to amend an authorization to possess shall be made to the Minister by the holder of the authorization when a change occurs with respect to

(*a*) the symptom mentioned in the authorization;

(*b*) the medical condition, or its treatment, with which the symptom is associated; or

(*c*) the recommended daily dosage of dried marihuana, if the new dosage is in excess of five grams.

(2) The application must include

(*a*) the authorization number;

(*b*) the requested amendment and supporting reasons; and

(*c*) the material required under sections 4 to 10.

20. (1) Subject to section 21, if an application complies with section 19, the Minister shall allow the amendment.

(2) If the authorization to possess is amended under subsection (1) with respect to the recommended dosage of dried marihuana, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization to reflect the change in the maximum number of marihuana plants that the holder may produce and the maximum quantity of dried marihuana that the holder may keep.

21. The Minister shall refuse to amend an authorization to possess for any reason referred to in section 12.

Notice of Change of Information

22. (1) The holder of an authorization to possess shall, within 10 days after the occurrence, notify the Minister in writing of a change in

(*a*) the holder's name;

(*b*) the holder's address of ordinary residence and mailing address, if different; or

(*c*) the daily dosage of dried marihuana recommended under paragraph 6(1)(*c*), if the new dosage is not in excess of five grams.

(2) The notice of change must be accompanied

(*a*) in the case of a change under paragraph (1)(*a*), by proof of the change;

(*b*) in the case of a change under paragraph (1)(*c*), by a statement, dated and signed by the medical practitioner or specialist of the holder of the authorization, certifying the new daily dosage recommended for the holder; and

(*c*) if a designated-person production licence has been issued on the basis of the authorization, by a statement indicating the name of the designated person who is the holder of the licence.

(3) On receiving a notice that complies with subsection (2), the Minister shall amend the authorization to reflect the change stated in the notice.

(4) If the authorization to possess is amended under subsection (3) with respect to the name or address of the holder of the authorization, the Minister shall, if applicable, amend accordingly the licence to produce that was issued on the basis of the authorization.

(5) If the authorization to possess is amended under subsection (3) with respect to the recommended dosage of dried marihuana, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization to reflect the change in the maximum number of marihuana plants that the holder may produce and the maximum quantity of dried marihuana that the holder may keep.

Providing Assistance to Holder

23. While in the presence of the holder of an authorization to possess and providing assistance in the administration of the daily dosage of marihuana to the holder, the person providing the assistance may, for the purpose of providing the assistance, possess a quantity of dried marihuana not exceeding the recommended daily dosage for the holder.

PART 2

LICENCE TO PRODUCE

Personal-use Production Licence

Authorized Activities

24. The holder of a personal-use production licence is authorized to produce and keep marihuana, in accordance with the licence, for the medical purpose of the holder.

Eligibility for Licence

25. Subject to subsection (2), a person is eligible to be issued a personal-use production licence only if the person is an individual ordinarily resident in Canada who has reached 18 years of age.

(2) If a personal-use production licence is revoked under paragraph 63(2)(*b*), the person who was the holder of the licence is ineligible to be issued another personal-use production licence during the period of 10 years after the revocation,

Priority of Application for Authorization

26. (1) An application for a personal-use production licence shall be considered only if it is made by a person who

(*a*) is the holder of an authorization to possess on the basis of which the licence is applied for; or

(*b*) is not the holder of an authorization to possess but either has applied for an authorization to possess, or is applying for an authorization to possess concurrently with the licence application.

(2) If paragraph (1)(*b*) applies, the Minister must grant or refuse the application for an authorization before considering the licence application.

Application for Licence

27. (1) A person mentioned in subsection 26(1) who is seeking a personal-use production licence shall submit an application to the Minister.

(2) The application must include

(*a*) a declaration of the applicant; and

(*b*) if the proposed production site is not the ordinary place of residence of the applicant and is not owned by the applicant, a declaration made by the owner of the site consenting to the production of marihuana at the site.

(3) The application may not be made jointly with another person.

Applicant's Declaration

28. (1) The declaration of the applicant under paragraph 27(2)(*a*) must indicate

(*a*) the applicant's name, date of birth and gender;

(*b*) the full address of the place where the applicant ordinarily resides as well as the applicant's telephone number and, if applicable, facsimile transmission number and e-mail address;

(*c*) the mailing address of the place referred to in paragraph (*b*), if different;

(*d*) if the applicant is the holder of an authorization to possess, the number of the authorization;

(*e*) the full address of the site where the proposed production of marihuana is to be conducted;

(*f*) the proposed production area;

(*g*) if the proposed production area involves outdoor production entirely or partly indoor and partly outdoor production, that the production site is not adjacent to a school, public playground, day care facility or other public place frequented mainly by persons under 18 years of age;

(*h*) that the dried marihuana will be kept indoors and indicating whether it is proposed to keep it at

(i) the proposed production site, or

(ii) the ordinary place of residence of the applicant, if different; and

(*i*) a description of the security measures that will be implemented at the proposed production site and the proposed site where dried marihuana will be kept.

(2) The declaration must be dated and signed by the applicant and attest that the information contained in it is correct and complete.

Issuance of Licence

29. (1) Subject to section 32, if the requirements of sections 27 and 28 are met, the Minister shall issue a personal-use production licence to the applicant.

(2) The licence shall indicate

(*a*) the name, date of birth and gender of the holder of the licence;

(*b*) the full address of the place where the holder ordinarily resides;

(*c*) the licence number;

(*d*) the full address of the site where the production of marihuana is authorized;

(*e*) the authorized production area;

(*f*) the maximum number of marihuana plants that may be under production at the production site at any time;

(*g*) the full address of the site where the dried marihuana may be kept;

(*h*) the maximum quantity of dried marihuana, in grams, that may be kept at the site referred to in paragraph (*g*) at any time;

(*i*) the date of issue; and

(*j*) the date of expiry.

Maximum Number of Plants

30. (1) In the formulas in subsection (2),

(*a*) "A" is the daily dosage of dried marihuana, in grams, recommended for the applicant under paragraph 6(1)(*c*), 19(1)(*c*) or 22(2)(*b*), whichever applies;

(*b*) "C" is a constant equal to 1, representing the growth cycle of a marihuana plant from seeding to harvesting; and

(*c*) "D" is the maximum number of marihuana plants referred to in subsections 20(2) and 22(5) and paragraphs 29(2)(*f*) and 40(2)(*g*).

(2) The maximum number of marihuana plants referred to in paragraph (1)(*c*) is determined according to whichever of the following formulas applies:

(*a*) if the production area is entirely indoors,

$$D = [(A \times 365) \div (B \times 3C)] \times 1.2$$

where B is 30 grams, being the expected yield of dried marihuana per plant,

(*b*) if the production area is entirely outdoors,

$$D = [(A \times 365) \div (B \times C)] \times 1.3$$

where B is 250 grams, being the expected yield of dried marihuana per plant; and

(*c*) if the production area is partly indoors and partly outdoors,

(i) for the indoor period

$$D = [(A \times 182.5) \div (B \times 2C)] \times 1.2$$

where B is 30 grams, being the expected yield of dried marihuana per plant, and

(ii) for the outdoor period

$$D = [(A \times 182.5) \div (B \times C)] \times 1.3$$

where B is 250 grams, being the expected yield of dried marihuana per plant.

(3) If paragraph (2)(*c*) applies, the maximum number of marihuana plants for both periods of production shall be mentioned in the licence to produce.

(4) If the number determined for D is not a whole number, it shall be rounded to the next-highest whole number.

Maximum Quantity of Dried Marihuana in Storage

31. (1) In the formula in this subsection (2),

(*a*) "D" is,

(i) if the production area is entirely indoors or outdoors, the maximum number of marihuana plants that the holder of the licence to produce is authorized to produce, calculated under paragraphs 30(2)(*a*) or (*b*), whichever applies,

(ii) if the production area is partly indoors and partly outdoors, the maximum number of marihuana plants that the holder of the licence to produce is authorized to produce, calculated under subparagraph 30(2)(*c*)(ii); and

(*b*) "E" is the maximum quantity of dried marihuana mentioned in paragraphs 20(2) and 22(5) and in paragraphs 29(2)(*h*) and 40(2)(*i*).

(2) The maximum quantity of dried marihuana referred to in paragraph (1)(*b*) is determined according to whichever of the following formulas applies:

(*a*) if the production area is entirely indoors,

$$E = D \times B \times 1.5$$

where B is 30 grams, being the expected yield of dried marihuana per plant,

(*b*) if the production area is entirely outdoors,

$$E = D \times B \times 1.5$$

where B is 250 grams, being the expected yield of dried marihuana per plant, and

(*c*) if the production area is partly indoors and partly outdoors,

$$E = D \times B \times 1.5$$

where B is 250 grams, being the expected yield of dried marihuana per plant.

Grounds for Refusal

32. The Minister shall refuse to issue a personal-use production licence if

(*a*) the applicant is not a holder of an authorization to possess;

(*b*) the applicant is not eligible under section 25;

(*c*) any information or statement included in the application is false or misleading;

(*d*) the proposed production site would be a site for the production of marihuana under more than three licences to produce; or

(*e*) the applicant would be the holder of more than one licence to produce.

Expiry of Licence

33. A personal-use production licence expires on the earlier of

(*a*) 12 months after its date of issue, and

(*b*) the date of expiry of the authorization to possess held by the licence holder.

Designated-person Production Licence

Authorized Activities

34. (1) The holder of a designated-person production licence is authorized, in accordance with the licence,

(*a*) to produce marihuana for the medical purpose of the person who applied for the licence;

(*b*) to possess and keep, for the purpose mentioned in paragraph (*a*), a quantity of dried marihuana not exceeding the maximum quantity specified in the licence;

(*c*) if the production site specified in the licence is different from the site where dried marihuana may be kept, to transport directly from the first to the second site a quantity of marihuana not exceeding the maximum quantity that may be kept under the licence;

(*d*) if the site specified in the licence where dried marihuana may be kept is different from the place where the person who applied for the licence ordinarily resides, to transport directly from that site to the place of residence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued; and

(*e*) to transfer, give or deliver directly to the person who applied for the licence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued.

(2) No consideration may be obtained for any activity authorized under subsection (1).

Eligibility for Licence

35. A person is eligible to be issued a designated-person production licence only if the person is an individual ordinarily resident in Canada who

(*a*) has reached 18 years of age; and

(*b*) has not been found guilty, within the 10 years preceding the application, of

(i) a designated drug offence, or

(ii) an offence committed outside Canada that, if committed in Canada, would have constituted a designated drug offence.

Priority of Application for Authorization

36. (1) An application for a designated-person production licence shall be considered only if it is made by a person who

(*a*) is the holder of an authorization to possess on the basis of which the licence is applied for; or

(*b*) is not the holder of an authorization to possess, but either has applied for an authorization to possess or is applying for an authorization to possess concurrently with the licence application.

(2) If paragraph (1)(*b*) applies, the Minister must grant or refuse the application for an authorization before considering the licence application.

Application for Licence

37. (1) A person mentioned in subsection 36(1) who is seeking to have a designated-person production licence issued to a designated person shall submit an application to the Minister.

(2) The application must include

(*a*) a declaration by the applicant;

(*b*) a declaration by the designated person;

(*c*) if the proposed production site is not the ordinary place of residence of the applicant and is not owned by the applicant, a declaration made by the owner of the site consenting to the production of marihuana at the site;

(*d*) a document issued by a Canadian police force establishing that, in respect of the 10 years preceding the application, the designated person does not have a criminal record as an adult for a designated drug offence; and

(*e*) two copies of a current photograph of the designated person that complies with the standards in paragraphs 10(*a*) to (*c*) and is certified by the applicant, on the reverse side, to be an accurate representation of the designated person.

(3) The application may not be made jointly with another person.

Applicant's Declaration

38. (1) The declaration of the applicant under paragraph 37(2)(*a*) must

(*a*) include the information referred to in paragraphs 28(1)(*a*) to (*d*);

(*b*) indicate the name, date of birth and gender of the designated person;

(*c*) indicate the full address of the place where the designated person ordinarily resides as well as the designated person's telephone number and, if applicable, facsimile transmission number and e-mail address; and

(*d*) indicate the mailing address of the place referred to in paragraph (*c*), if different.

(2) The declaration must be dated and signed by the applicant and attest that the information contained in the declaration is complete and correct.

Designated Person's Declaration

39. (1) The declaration of the designated person under paragraph 37(2)(*b*) must

(*a*) include the information referred to in paragraphs 28(1)(*e*) to (*g*) and (*i*);

(*b*) indicate that the dried marihuana will be kept indoors and whether it is proposed to keep it at:

(i) the proposed production site, or

(ii) the ordinary place of residence of the designated person, if the proposed production site is not the ordinary place of residence of the applicant; and

(*c*) indicate that, within the 10 years preceding the application, the designated person has not been convicted of

(i) a designated drug offence, or

(ii) an offence that, if committed in Canada, would have constituted a designated drug offence.

(2) The declaration must be dated and signed by the designated person and attest that the information contained in it is correct and complete.

Issuance of Licence

40. (1) Subject to section 41, if the requirements of sections 37 to 39 are met, the Minister shall issue a designated-person production licence to the designated person.

(2) The licence shall indicate

(*a*) the name, date of birth and gender of the holder of the licence;

(*b*) the name, date of birth and gender of the person for whom the holder of the licence is authorized to produce marihuana and the full address of that person's place of ordinary residence;

(*c*) the full address of the place where the holder of the licence ordinarily resides;

(*d*) the licence number;

(*e*) the full address of the site where the production of marihuana is authorized;

(*f*) the authorized production area;

(*g*) the maximum number of marihuana plants that may be under production at the production site at any time;

(*h*) the full address of the site where the dried marihuana may be kept;

(*i*) the maximum quantity of dried marihuana that may be kept at the site authorized under paragraph (*h*) at any time;

(*j*) the date of issue; and

(*k*) the date of expiry.

Grounds for Refusal

41. The Minister shall refuse to issue a designated-person production licence

(*a*) if the designated person is not eligible under section 35;

(*b*) the designated person would be the holder of more than one licence to produce; or

(*c*) for any reason referred to in paragraphs 32(*a*) to (*d*).

Expiry of Licence

42. A designated-person production licence expires on the earlier of

(*a*) 12 months after its date of issue, and

(*b*) the date of expiry of the authorization to possess on the basis of which the licence was issued.

General Provisions

Renewal of Licence to Produce

43. An application to renew a licence to produce shall be made to the Minister by the person who applied for the licence and shall include

(*a*) the licence number; and

(*b*) the material required under sections 27 and 28 or under sections 37 to 39, whichever apply.

44. Subject to section 45, if an application complies with section 43, the Minister shall renew the licence to produce.

45. The Minister shall refuse an application to renew a licence to produce for any reason referred to in section 32 or 41, whichever applies.

Change of Production Site or Production Area

46. (1) A person who applied for a licence to produce shall submit an application to the Minister to amend the licence if the person proposes to change the location of the production site or the production area.

(2) The application under subsection (1) shall include

(*a*) the licence number;

(*b*) in the case of a proposed change of production site, the full address of the proposed new site and supporting reasons for the proposed change;

(*c*) in the case of a proposed change of production area, the proposed new production area and supporting reasons for the proposed change; and

(*d*) the material required under sections 27 and 28 or sections 37 to 39, whichever apply.

47. Subject to section 48, if an application complies with subsection 46(2), the Minister shall amend the licence to produce.

48. The Minister shall refuse to amend a licence to produce for any reason referred to in section 32 or 41, whichever applies.

Change of Site Where Dried Marihuana Is Kept

49. (1) If the holder of a licence to produce proposes to change the location of the site where dried marihuana is kept, the holder shall apply to the Minister in writing, not less than 15 days before the intended effective date of the change.

(2) The application shall indicate

(*a*) the new site, selected from among those permitted under paragraph 28(1)(*h*) or 39(1)(*b*), whichever applies; and

(*b*) the intended effective date of the change.

(3) On receipt of an application that complies with subsection (2), the Minister shall amend the licence to reflect the change stated in the application.

Notice of Change of Information

50. (1) The holder of a licence to produce shall, within 10 days after the occurrence, notify the Minister in writing of

(*a*) a change in the holder's name; or

(*b*) subject to subsection (2), a change in the holder's address of ordinary residence.

(2) If the holder's address of ordinary residence is also the address of the site for the production of marihuana under the licence, the holder shall make an application under section 46.

(3) A notice under paragraph (1)(*a*) must be accompanied by proof of the change.

(4) On receiving a notice that complies with subsection (3), the Minister shall amend the licence to produce to reflect the change stated in the notice.

Marihuana Seed

51. (1) The Minister, and any person designated by the Minister under section 57 of the Act, is authorized to import and possess marihuana seed for the purpose of selling, providing, transporting, sending or delivering the seed in accordance with this section.

(2) The persons referred to in subsection (1) may sell, provide, transport, send or deliver marihuana seeds only to

(*a*) the holder of a licence to produce; or

(*b*) a licensed dealer under the *Narcotic Control Regulations*.

Restrictions

52. The holder of a licence to produce may produce marihuana only at the production site authorized in the licence and only in accordance with the authorized production area.

53. If the production area for a licence to produce permits the production of marihuana entirely outdoors or partly indoors and partly outdoors, the holder shall not produce marihuana outdoors if the production site is adjacent to a school, public playground, day care facility or other public place frequented mainly by persons under 18 years of age.

54. The holder of a licence to produce shall not produce marihuana in common with more than two other holders of licences to produce.

55. The holder of a licence to produce may keep dried marihuana only indoors at the site authorized in the licence for that purpose.

Records

56. (1) The holder of a designated-person production licence must, at either the production site or the site where dried marihuana may be kept, maintain records of the following information in respect of the licence:

(*a*) the number of plants grown;

(*b*) the date each plant was planted from seed or by transplant;

(*c*) the date each plant was harvested; and

(*d*) for each plant harvested, the weight in grams of dried marihuana obtained.

(2) The information referred to in subsection (1) shall be retained for at least two years after it is recorded.

(3) On request, the holder of a designated-person production licence must provide the Minister with a copy of any record referred to in subsection (1).

Inspection

57. (1) To verify that the production of marihuana is in conformity with these Regulations and a licence to produce, an inspector may, at any reasonable time, enter any place where the inspector believes on reasonable grounds that marihuana is being

produced or kept by the holder of the licence to produce, and may, for that purpose,

(*a*) open and examine any container found there that could contain marihuana;

(*b*) examine anything found there that is used or is capable of being used to produce or keep marihuana;

(*c*) examine any records, electronic data or other documents found there dealing with marihuana, other than records dealing with the medical condition of a person, and make copies or take extracts;

(*d*) use, or cause to be used, any computer system found there to examine electronic data referred to in paragraph (*c*);

(*e*) reproduce, or cause to be reproduced, any document from electronic data referred to in paragraph (*c*) in the form of a printout or other output;

(*f*) take any document or output referred to in paragraph (*c*) or (*e*) for examination or copying;

(*g*) examine any substance found there and, for the purpose of analysis, take samples, as reasonably required; and

(*h*) seize and retain any substance found there, if the inspector believes, on reasonable grounds, that it is necessary.

(2) Despite subsection (1), an inspector may not enter a dwelling-place without the consent of an occupant.

PART 3

OBLIGATIONS CONCERNING DOCUMENTS AND REVOCATION

Showing Documents

58. (1) On demand, the holder of an authorization to possess must show proof of their authority to possess dry marihuana to a police officer.

(2) On demand, the holder of a licence to produce must show the licence to a police officer.

Unauthorized Changes

59. No one may add to, delete or obliterate from, or alter in any other way, an authorization to possess or a licence to produce.

Return of Documents

60. (1) If an authorization to possess or licence to produce is renewed or amended, the holder of the authorization or licence shall, within 30 days after receiving the new document, return the replaced document to the Minister.

(2) If an authorization to possess or licence to produce expires without being renewed or is revoked, the holder of the authorization or licence shall, within 30 days after the occurrence, return the expired or revoked document to the Minister.

Security and Reporting Loss or Theft

61. (1) The holder of an authorization to possess or a licence to produce shall maintain measures necessary to ensure the security of the marihuana in their possession as well as the authorization or licence, or both, issued to them.

(2) In the case of the loss or theft of marihuana or of the holder's authorization or licence, the holder of the authorization or licence shall, on becoming aware of the occurrence,

(*a*) within the next 24 hours, notify a member of a police force; and

(*b*) within the next 72 hours, notify the Minister, in writing, and include confirmation that the notice required under paragraph (*a*) has been given.

Revocation

62. (1) The Minister shall revoke the authorization to possess and any licence to produce issued on the basis of the authorization, if the holder of an authorization requests that the authorization be revoked.

(2) Subject to section 64, the Minister shall revoke an authorization to possess and any licence to produce issued on the basis of the authorization if

(*a*) the holder of the authorization is not eligible under section 3;

(*b*) a medical practitioner for the holder of the authorization advises the Minister in writing that the use of marihuana by the holder is no longer recommended;

(*c*) the authorization was issued on the basis of false or misleading information; or

(*d*) the photograph submitted under paragraph 4(2)(*d*) or section 14 as part of the application for the authorization or renewal is not an accurate representation of the holder of the authorization.

63. (1) On request by the holder of a licence to produce, the Minister shall revoke the licence.

(2) Subject to section 64, the Minister shall revoke a licence to produce if

(*a*) the holder is not eligible under section 25 or 35, whichever applies;

(*b*) the holder of a personal-use production licence is found guilty of a designated marihuana offence committed after the date of issue of the licence;

(*c*) the holder of a designated-person production licence is found guilty of a designated drug offence committed after the date of issue of the licence;

(*d*) the holder of a licence to produce marihuana outdoors produces marihuana in contravention of section 53;

(*e*) the photograph submitted under paragraph 37(2)(*e*) or section 43 as part of the application for a designated-person production licence or renewal is not an accurate representation of the designated person; or

(*f*) the licence to produce was issued on the basis of false or misleading information.

64. The Minister shall not revoke an authorization to possess or a licence to produce under section 62 or 63 unless

(*a*) the Minister has given the holder of the authorization or licence written notice of the reasons for the proposed revocation; and

(*b*) the holder has been given an opportunity to be heard.

Destruction of Marihuana

65. (1) If an authorization to possess expires without being renewed or is revoked, the holder shall destroy all marihuana in their possession.

(2) If a licence to produce expires without being renewed or is revoked, the holder of the licence shall discontinue production of marihuana and, subject to section 66, destroy all marihuana in their possession.

(3) Within 10 days after destroying the marihuana, the holder of the authorization or the licence shall notify the Minister, in writing, of the amount of marihuana destroyed.

66. (1) If a personal-use production licence expires without being renewed but the holder remains the holder of a valid authorization to possess, the holder is not required to destroy dried marihuana that is not in excess of the maximum quantity permitted under the authorization.

(2) If a designated-person production licence expires without being renewed but the authorization to possess on the basis of which the licence was issued remains valid, the holder of the licence, before destroying marihuana, may immediately transport, transfer, give or deliver directly to the holder of the authorization not more than a quantity of dried marihuana that results in the holder of the authorization being in possession of the maximum quantity permitted under the authorization.

67. (1) If a licence to produce is amended under section 47 or at the time of the renewal to reflect an change in the production area, the holder of the licence must destroy any marihuana plants in production under the licence that are in excess of the maximum number of plants that may be produced under the licence, as changed.

(2) If a licence to produce is amended under section 47 or at the time of the renewal to reflect an change in the production area, the holder of the licence must destroy any dried marihuana kept under the

licence that is in excess of the maximum quantity of marihuana that may be kept under the licence, as changed.

Complaints and Disclosure of Information

68. (1) An inspector shall receive and make a written record of any complaint from the public concerning a person who is a holder of an authorization to possess or licence to produce with respect to their possession or production of marihuana.

(2) The inspector shall report to the Minister any complaint recorded under subsection (1).

(3) The Minister may communicate to any police force in Canada or any member of a police force in Canada, any information contained in the report of the inspector, subject to that information being used only for the proper enforcement or administration of the Act or these Regulations.

69. The Minister may provide, in writing, any factual information that has been obtained about a medical practitioner under the Act or these Regulations to the licensing authority responsible for the registration or authorization of the person to practise medicine

(*a*) in the province in which the medical practitioner is authorized to practise if

(i) the authority submits to the Minister a written request that sets out the name and address of the medical practitioner, a description of the information being sought and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or

(ii) the Minister has reasonable grounds to believe that the medical practitioner has

(A) contravened a rule of conduct established by the authority,

(B) been found guilty in a court of law of a designated drug offence, or

(C) made a false statement under these Regulations; or

(*b*) in a province where the medical practitioner is not authorized to practise, if the authority submits to the Minister

(i) a written request for information that sets out

(A) the name and address of the medical practitioner, and

(B) a description of the information being sought, and

(ii) documentation that shows that the medical practitioner has applied to that authority to practise in that province.

PART 4

SUPPLY BY A MEDICAL PRACTITIONER

70. A medical practitioner who has obtained marihuana from a licensed dealer under subsection 24(2) of the *Narcotic Control Regulations* may sell or furnish the marihuana to the holder of an authorization to possess under the practitioner's care.

NARCOTIC CONTROL REGULATIONS

71. Paragraph 53(1) of the *Narcotic Control Regulations*[1] is replaced by the following:

53. (1) No practitioner shall administer, prescribe, give, sell or furnish a narcotic to any person or animal except as authorized under this section or the *Marihuana Medical Access Regulations*.

TRANSITIONAL PROVISION

72. If, on the coming into force of these Regulations, a person is, for a medical purpose, exempt under section 56 of the Act from the application of subsection 4(1) and, if applicable, section 7 of the Act in respect of marihuana, the person is, by virtue of this section, exempt from those provisions for a period of six months after the date of expiry for the section 56 exemption, on the same terms and conditions as those contained in the section 56 exemption

[1] C.R.C., c. 1041

except for any term or condition pertaining to the expiry date of the exemption.

COMING INTO FORCE

73. These Regulations come into force on July 30, 2001.

SCHEDULE

(Section 1)

CATEGORY 2 SYMPTOMS

Column 1 Medical Condition	Column 2 Symptom
Cancer, AIDS, HIV infection	Severe nausea
Cancer, AIDS, HIV infection	Cachexia, anorexia, weight loss
Multiple sclerosis, spinal cord injury or disease	Persistent muscle spasms
Epilepsy	Seizures
Cancer, AIDS, HIV infection, multiple sclerosis, spinal cord injury or disease, severe form of arthritis	Severe pain

REGULATORY IMPACT ANALYSIS STATEMENT
(This statement is not part of the Regulation)

Description

The *Marihuana Medical Access Regulations* (Regulations) provide seriously ill Canadian patients with access to marihuana while it is being researched as a possible medicine. These Regulations have been developed in recognition of a need for a more defined process than the one currently used under section 56 of the *Controlled Drugs and Substances Act* (CDSA) for these Canadian patients.

On July 31, 2000, the Court of Appeal for Ontario rendered its decision in the case of Terrance Parker who uses marihuana to help control his epilepsy. The Court dealt exclusively with the issue of medical use of marihuana. The Court upheld a 1997 lower court decision to stay the charges against Mr. Parker on constitutional grounds and raised issues related to the section 56 exemption process of the CDSA, such as the broad discretion given by the law to the Minister of Health to grant exemptions, transparency of the process, and what constitutes medical necessity.

As a result, the Court declared the prohibition of marihuana in the CDSA to be unconstitutional and of no force and effect. The declaration of invalidity was suspended for a year, however, to avoid leaving a gap in the regulatory scheme.

Subsequent to this Court decision, Health Canada announced on September 14, 2000, its intention to develop a new regulatory approach for Canadians to access marihuana. This new approach would bring greater clarity to the process for those Canadians who may request the use of marihuana to alleviate symptoms.

The new Regulations clearly define the circumstances and the manner in which access to marihuana for medical purposes will be permitted. These Regulations appropriately and efficiently address concerns raised in the Parker decision concerning the process currently used under section 56 of the CDSA. These Regulations apply only to marihuana.

Legislative Framework

International

The United Nations (UN) has developed a system for the global control of narcotic drugs and psychotropic substances through a series of drug control Conventions. The UN *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs* (1961 Convention), the UN *Convention on Psychotropic Substances, 1971* (1971 Convention) and the UN *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* (1988 Convention) set out a system of controls relating to the international production and distribution of narcotic drugs and psychotropic substances.

Under the 1961 Convention, parties have agreed to enact legislation that strictly controls the cultivation and distribution of opium poppy, coca and marihuana plants, and the production and distribution of other narcotics. All production, distribution and use of any substance listed under this convention must be limited to scientific or medical purposes.

Under the 1971 Convention, psychoactive substances are to be subjected to controls similar to those that apply under the 1961 Convention. THC (delta-9-tetrahydrocannabinol) and other isolated marihuana derivatives, known as cannabinoids, are listed under this Convention.

Under the 1988 Convention, parties must cooperatively take action to control illicit cultivation, production and distribution of drugs of abuse. This includes the cultivation of marihuana.

Canada

Controlled Drugs and Substances Act

The *Controlled Drugs and Substances Act* (CDSA) prohibits possession, double doctoring, trafficking, possession for the purpose of trafficking, importation, exportation and possession for the purpose of exporting and production of substances included in schedules to the CDSA. These

activities are illegal unless authorized in Regulations made under the CDSA.

The Regulations currently in force under the CDSA:

- govern the activities of producers, distributors, importers, exporters, researchers and health care professionals relating to controlled drugs and substances used for scientific or medical purposes and, in the case of hemp, for industrial purposes;
- require all dealers to be licensed to produce, distribute, import and export controlled drugs and substances;
- regulate the distribution of controlled drugs and substances by pharmacists, practitioners and hospitals and outline the records that must be kept to account for the distribution of these drugs.

One set of these Regulations, the *Narcotic Control Regulations,* regulates the legal distribution of “narcotic” drugs such as opium, codeine, morphine, heroin, cocaine, and *Cannabis* (marihuana).

Food and Drugs Act and Regulations

Drugs are approved for sale in Canada under the *Food and Drugs Act* and *Regulations*. The *Food and Drug Regulations* provide controls respecting the safety, efficacy and quality of products offered for sale in Canada as well as the importation, distribution and sale of approved drugs.

Marihuana has not been reviewed for safety or effectiveness and has therefore not been approved for sale as a drug in Canada or any other country. Most scientific experts assert that marihuana’s future as a drug lies primarily in its pharmacologically active components, the cannabinoids. These chemicals can be isolated, subjected to scientific scrutiny and potentially developed as standardized pharmaceutical drug products.

Within the full set of approved pharmaceutical treatments available to patients there are two commercially available drugs related to marihuana: MARINOL®, which contains chemically synthesized THC; and CESAMET®, a synthetic cannabinoid. In Canada, both drugs are approved for the treatment or management of severe nausea and vomiting associated with cancer chemotherapy and may be prescribed by

physicians. MARINOL® has also been approved for the treatment of anorexia associated with weight loss in patients with AIDS. Both drugs are taken orally and must be prescribed by a physician.

Marihuana for Medical Purposes

Therapeutic Claims and Uses

Claims of potential therapeutic benefit of marihuana are usually for symptomatic relief rather than for curative relief. The main claimed therapeutic uses are:

- **Nausea and vomiting**: For the relief of nausea and vomiting associated with cancer and AIDS therapies.
- **Wasting syndrome**: To stimulate appetite and produce weight gain in AIDS and cancer patients.
- **Multiple sclerosis:** For the relief of muscle pain and spasms.
- **Epilepsy:** To help reduce the frequency of epileptic seizures.

Much of the evidence of the potential therapeutic effects of smoked marihuana is heavily anecdotal. Scientific studies supporting the safety and efficacy of marihuana for therapeutic use are often inconclusive.

Adverse Health Effects

The potential health risks associated with the use of marihuana for medical purposes have not been adequately examined. The main known adverse health effects for smoked marihuana include:

- **Dependance:** There is clinical and epidemiological evidence that some heavy marihuana users experience problems in controlling marihuana use. A distinctive marihuana withdrawal syndrome has been identified, although it is mild and short-lived.
- **Psychomotor skills**: Marihuana reduces the ability to perform tasks requiring concentration and coordination such as driving a car.
- **Respiratory:** Marihuana causes lung damage similar to that caused by tobacco smoke. These long-term risks must be

considered in long term use by patients with chronic diseases. They may be of lesser concern where short-term use of marihuana is being proposed.

- **Cardiovascular:** Marihuana increases heart rate and blood pressure.
- **Immune system:** Though the complete effects of marihuana on immune function remain unknown, it is suspected that marihuana may have an adverse effect on the immune system.

Research into the use of marihuana for medical purposes may eventually bring new pharmaceutical products to market that contain marihuana components. Until that time however, patients, particularly those with serious medical conditions where conventional treatments may offer little hope of relief, are demanding access to marihuana for personal medical use.

International Perspective

Currently, marihuana is not approved as a drug in any country in the world. Some countries and U.S. States are actively reviewing their policies and laws concerning the medical use of marihuana. Several have already allowed or are considering allowing some form of access to marihuana for medical purposes.

What follows are examples of initiatives currently under way relating to permitting certain medical uses of marihuana and the production and distribution of marihuana for medical purposes, as well as research projects attempting to validate the various medical claims being made for marihuana.

United States

In the United States, several individual states have enacted legislation whereby patients who suffer from certain serious or debilitating medical conditions may be granted authorization to possess marihuana for personal medical use. Patients may also be permitted to grow marihuana for this purpose, since there would otherwise be no legitimate supply.

To date, eight states, including Oregon, Hawaii and Alaska, have enacted laws which authorize the legal possession and medical use of marihuana, even though these laws may conflict with current federal laws.

In January 1997, the White House Office of National Drug Control Policy (ONDCP) asked the Institute of Medicine (IOM) to conduct a review of the scientific evidence to assess the potential health benefits and risks of marihuana and its constituent cannabinoids. That review began in August 1997 and culminated with a report issued in 1999, *Marijuana and Medicine - Assessing the Science Base.* This report provided a summary of current scientific knowledge on the potential medical use of marihuana and is being used to guide medical research not only in the U.S. but around the world.

More recently, on April 18, 2001, the U.S. Drug Enforcement Agency published its denial of a petition to reschedule marihuana. The notice includes a lengthy review of the research; it states that since marihuana has no established medical use, and its harmful and addictive effects are well documented, it will remain a Schedule 1 drug, illegal to manufacture, distribute or dispense in the U.S.

On May 14, 2001, the U.S. Supreme Court ruled that marihuana's classification as an illegal drug is valid in an unanimous
(8-0) decision *(United States v. Oakland Buyers Co-operative)*. The judges wrote that, "the statute reflects a determination that marijuana has no medical benefits worthy of an exemption (outside the confines of a government-approved research project)," and noted that Congress has decided that marihuana "has no currently accepted medical use."

While this ruling means that the manufacture and distribution of marihuana continues to be illegal in the U.S., which includes the activities of buyers clubs, co-operatives, compassion clubs and so called "pot pharmacies," it does not directly address or quash state laws or initiatives which permit patients to grow, possess and use marihuana for medical purposes.

Australia

The medical use of marihuana is currently prohibited in all states and territories of Australia. However, the government of New South Wales (NSW) commissioned a report, which was completed in August 2000, to advise the NSW government on whether to allow patients with certain medical conditions to use cannabis (marihuana). The government of NSW also sought input on how best to allow the medical use of marihuana

without promoting the recreational use of the drug. The Working Party on the Use of Cannabis for Medical Purposes made specific recommendations for consideration by the government. These recommendations are now under consideration by the NSW government as it assesses the feasibility of using marihuana for medical purposes.

Netherlands

In December 2000, the Ministry of Health, Welfare and Sport of the Netherlands announced its intention to establish an Office of Medicinal Cannabis on January 1, 2001. The goals of this office are to determine whether marihuana may be useful as a medicine. The office will also be the regulator for the production of cannabis for medical research purposes.

Canada

In June 1999, Health Canada published a document entitled *Research Plan for Marihuana for Medicinal Purposes: A Status Report*. This document set out a research plan for determining the risks and benefits of the use of marihuana for medical purposes. It included the following elements:

- a research agenda composed of projects to address the issues of the safety and efficacy of smoked marihuana and of cannabinoids;
- a mechanism (i.e. section 56 of the CDSA) for medical access to marihuana outside of the research projects; and,
- activities to develop a Canadian source of research-grade marihuana.

Since the publication of that document, Health Canada has made significant progress on each element of the research plan. Research projects are being developed, a contract has been awarded for the establishment of a domestic source of research-grade marihuana and approximately 250 exemptions allowing patients to possess and produce marihuana for their personal medical purposes have been granted. These Regulations replace the current exemption process with a formal and more transparent process.

Proposed Regulatory Approach

Due to the health risks associated with the smoked form in particular, and due to the lack of evidence supporting the claimed health benefits, access to marihuana will be granted under these Regulations in special medical circumstances only: serious medical conditions, including terminal diseases, where conventional treatments may not provide adequate symptomatic relief.

The necessity to employ marihuana in any specific patient's case is deemed to be best determined by the medical practitioner as it is for the majority of drugs that are used therapeutically.

These Regulations contain two main components: "authorizations to possess" and "licences to produce."

Authorization to Possess

- An authorization to possess marihuana for medical purposes will be issued by Health Canada. The application requirements to obtain an authorization to possess will depend on the category under which the request is made. The requirements will range from minimal, in the case of terminal illness situations, to more substantive for non-terminal illness cases where little or no conclusive scientific evidence exists.

- All applications will be submitted by the patient, but must include a declaration from the patient's medical practitioner. Depending on the category under which the application is being made, support from a medical specialist may be required. These Regulations set out three categories.

- Category 1 is for patients who have terminal illnesses with a prognosis of death within 12 months. In this situation, the Regulations provide a less demanding process to obtain the authorization to possess because the risks associated with long-term use are not a major consideration. The Regulations will allow for one renewal under this category should the prognosis be inaccurate. Any subsequent renewals would have to be made under another category.

- Category 2 is for patients who suffer from specific symptoms associated with some serious medical conditions (examples include weight loss in patients with AIDS/HIV in a non-

terminal situation; persistent muscle spasms in multiple sclerosis). These symptoms are listed in a schedule to the Regulations. Symptoms associated with serious medical conditions in this category have been selected based on the outcome or conclusions of scientific and medical reports from medical organizations that have performed a review of available scientific literature (for example the IOM report previously mentioned). These reports confirm the existence of a certain amount of inconclusive scientific evidence to indicate a potential benefit but raise caution on the known risks of using a smoked form, particularly with respect to long term use. Seizures associated with epilepsy has been added to the list of symptoms in the schedule to the Regulations in view of the findings in the Parker case. Though the application under this category is to be submitted by the patient, specific statements from a medical specialist are required in support of the application. These statements include, among other things, that conventional treatments have been tried or at least considered and found not medically appropriate for the reasons outlined in the Regulations.

- Category 3 is for patients who have symptoms associated with medical conditions other than those in the other two categories. For this category, although the application will be submitted by the patient, specific statements from two medical specialists are required in support of the application. This is necessary since less conclusive scientific evidence exists supporting the use of marihuana in the treatment of symptoms associated with medical conditions not included in Category 2. All conventional therapies should have been tried or at least considered and found not medically appropriate for the reasons outlined in the Regulations. The list of therapies tried or considered will have to be submitted with the reasons as to why they were found medically inappropriate.

- For all three categories, the authorization to possess marihuana for a medical purpose will specify a maximum quantity of marihuana equal to a 30-day treatment supply at any given time. Quantity of supply will be continuously refurbished by quantities produced under the licence to produce. The daily dosage that determines the 30-day treatment supply is provided by the physician and will be subject to additional requirements when proposed dosage exceeds a quantity of 5 grams per day.

Licence to Produce

- A licence to produce marihuana will be issued to either the patient or a representative that the patient designates in the application. A representative cannot be designated by more than one patient. One site may, however, be used for the production of marihuana under a maximum of three separate licences. The licence will authorize and specify the production of a maximum number of plants, and whether they will be grown outdoors or indoors. This will allow flexibility when choosing a growing location and will accommodate the different yields produced by indoor and outdoor growing methods. The number of plants will be dependent upon the patient's daily dosage identified by the physician.

- The licence will also allow for storage and, in the case of a designated person, transportation of marihuana to the patient if the production is conducted at a site other than the patient's residence.

- The licence holder, whether the patient or his/her designated person, must take reasonable precautions to protect his/her plants and the dried marihuana in storage from loss or theft. The type of precautions to be taken are not specified in the Regulations, but will be left to the reasonable discretion of the licence holder.

- A criminal record check will be requested from the person designated by a patient to produce marihuana on his/her behalf. The proposed designated person will not be eligible if he/she has been found guilty of a designated drug offence in the previous ten years. This requirement is not imposed on the patient.

Other Provisions

- The disclosure to police of information concerning the holder of an authorization to possess and the holder of a licence to produce will require the voluntary consent of the holder of the authorization or licence to produce. The Regulations allow for referral to police of complaints received by Health Canada inspectors. Furthermore, provisions also exist to disclose information on medical practitioners to provincial licensing authorities of

medicine when requested for a lawful investigation by these authorities.

- Transitional provisions will extend the section 56 exemptions in effect at the time the Regulations come into force for an extra(6 months). As well, the coming into force date for these Regulations will be changed from July 15, to July 30, 2001, to allow the maximum amount of time for patients and physicians to become familiar with the new requirements.

- Instead of making the related regulatory amendments to the *Narcotic Control Regulations* (NCR) as described in the proposed Regulations which were pre-published in *Canada Gazette, Part I*, upon further consideration, it is deemed more appropriate to include the necessary provisions within the *Marihuana Medical Access Regulations* (MMAR) and make minimal changes to the NCR. These provisions allow for the potential supply of marihuana to an authorized person where the marihuana is obtained legally under the NCR or MMAR.

Alternatives Considered

The options outlined below provide an overview of the regulatory alternatives that were considered prior to the selection of option 1 as detailed in this Regulatory Impact Analysis Statement (RIAS).

Option 1: Develop new Regulations under the CDSA, distinct from the *Narcotic Control Regulations*, providing a system of special authorizations and licences permitting individual patients to possess and produce marihuana for the relief of symptoms associated with serious medical conditions or the treatment of these conditions.

Pros: Easier for the public to consult and understand as stand-alone Regulations; control measures of the new regulatory scheme will deal exclusively with the issues relating to access to marihuana for medical purposes; the resulting Regulations will be less complicated than attempting to incorporate these measures in existing Regulations; the regulatory regime could be established within the time available.

Cons: Creates two sets of Regulations under the CDSA that apply to marihuana; linkages required between Regulations create slight risk of confusion on some aspects.

Option 2: Amend existing *Narcotic Control Regulations* (NCR) to provide a system of special authorizations and licences to permit individual patients to possess and produce marihuana for the relief of symptoms associated with serious medical conditions or the treatment of these conditions.

Pros: All Regulations relating to marihuana would be within one set of regulations.

Cons: Necessary modifications to address marihuana for medical use would require extensive consultation to modernise the whole regulatory framework to accommodate the new provisions; time required to accomplish all this exceeds time available to implement new approach; the structure of the NCR does not easily lend itself to the addition of the proposed scheme; the amended NCR could become too complicated.

Option 3: Amend the CDSA to include a part dealing with access to marihuana for medical purposes.

Pros: Provides greater flexibility in the design and drafting of the regulatory scheme.

Cons: Cannot be completed within the time available; Regulatory schemes are not usually included in the Act itself; more difficult to amend when necessary to adapt to new information.

Each option was assessed against the following screening criteria. These criteria or considerations represent required outcomes or characteristics of the new regulatory approach for marihuana for medical purposes. The regulatory approach must:

- meet the mandatory requirements of all international drug control Conventions, to the extent possible, in consideration of the *Canadian Charter of Rights and Freedoms*;
- be developed and implemented by July 31, 2001;

- be clear and easy to implement, administer and enforce;
- not unduly restrict the availability of marihuana to patients who may receive health benefits from its use; and
- minimize any increase in regulatory burden on patients, medical practitioners, medical licensing authorities, and enforcement agencies.

Option 1 was determined to be the preferred option as it is the only option that meets all of the screening criteria for selection. It will create the most comprehensive and transparent process.

Benefits and Costs

Health Canada's exemption process operating under section 56 of the CDSA has been in place since May 1999. The new regulatory approach has been developed based on experience gained over the past two years. Under the new regulatory scheme, patients and medical practitioners who are already familiar with the requirements under the current system are offered a more transparent and less discretionary regulatory mechanism under which legitimate patients may obtain permission to possess and grow marihuana for their own medical purposes.

A Business Impact Test was not conducted on this proposal. That the activities allowing possession and production of marihuana for medical purposes are already being performed by Health Canada. Accordingly, the added cost and delay to conduct a Business Impact Test is deemed not to be warranted.

The cost of administering the current section 56 exemption process is borne by Health Canada, as the regulator. Similarly, the costs of the new authorization and licensing program will, at least initially, be borne by Health Canada. The costs of administering the new regulatory system will be reassessed following its implementation. No cost-recovery initiative would be contemplated without further consultation with stakeholders.

These regulations are expected to impact on the following sectors:

Public

Canadian patients, who suffer from serious medical conditions including terminal illnesses, whose symptoms may be relieved through the use of marihuana may qualify for authorization to possess marihuana and may also be granted a licence to produce marihuana for their own medical use. In addition, if a patient is not able to produce the marihuana, an alternate may be designated to perform this function on his/her behalf, again under licence. The regulatory framework defines what activities are permitted. Since patients will be permitted to possess and produce marihuana it may occur that these activities will be performed where they may conflict with the rights of others. Patients may need to be cautioned to avoid, for example, smoking marihuana in public places, near children or any place where others might be exposed to the second-hand smoke without prior consent.

Licensed Dealers

These Regulations will not impact on licensed dealers of controlled substances.

Pharmaceutical Industry

These Regulations will not impact the Canadian pharmaceutical industry in general, since only personal possession and production are addressed.

Practitioners

Activities of practitioners will be affected by these Regulations. There will be some increase in administrative activity for medical practitioners resulting from the necessity to provide a supporting medical declaration as part of the application.

In certain cases, additional statements or evidence may need to be submitted to support the application. This is due in part to the fact that the medical benefits of using marihuana in the treatment of symptoms associated with certain medical conditions have not been scientifically proven. The other reason is that the health risks associated with the use of marihuana, particularly in smoked form, make it essential for a medical practitioner to be involved in making this medical decision. In certain cases, the statements must be supplied by a medical specialist.

Pharmacists

Activities of pharmacists will not be affected by these Regulations. The potential involvement of pharmacists, either at the retail or hospital level, in the distribution of marihuana to patients who hold authorizations to possess marihuana will be contemplated in the future. Pharmacists could eventually play a key role in the distribution of marihuana products as they do today for pharmaceutical drugs.

Hospitals

Activities of hospitals should not be significantly affected by these Regulations.

A patient holding an authorization to possess and/or licence to produce marihuana may reside in a hospital or other health care institution. The decision to allow a patient to possess and/or grow marihuana within the institution remains the decision of that institution.

Correctional Institutions

As is the case for hospitals, the decision to allow an inmate to possess and/or grow marihuana within the penitentiaries, jails and other correctional institutions remains the decision of each institution.

Researchers

These Regulations do not affect the activities of researchers.

Canada Customs and Revenue Agency

These Regulations do not permit a patient to import or export marihuana for medical or any other purpose. Existing provisions under the CDSA continue to apply as before, prohibiting any person from importing or exporting marihuana. Although patients who hold authorizations to possess marihuana may attempt to take marihuana out of the country, this activity remains illegal. Customs officials may experience some increase in incidents involving marihuana. Clear guidelines to patients will be necessary to avoid such problems.

Law Enforcement Agencies

Police forces recognize that a regulatory system of authorizations and, at this time, licences to produce for personal medical purposes is required so that legitimate patients may have access to marihuana from a legal source. While Health Canada will manage the activities of authorizations and licences, the police will continue to investigate and enforce the provisions of the CDSA where activities are not permitted under an authorization or licence.

Health Canada

The regulatory scheme will ensure that authorizations are granted for legitimate medical reasons and that any production is done under licence. There will be increased costs to Health Canada associated with implementation of the Regulations, the processing of applications for authorizations and licences and the establishment and maintenance of relevant files and databases. Costs will also be incurred to develop guidelines and forms to support these Regulations as well as to establish a process for providing on-going information to patients, medical practitioners and the general public. There will also be costs associated with administration, investigation, inspection and reporting.

Ongoing impact on Health Canada is difficult to predict since the numbers of potential applicants is unknown at this time. Approximately 250 exemptions for medical purposes have been granted under the existing section 56 exemption process. Due to anticipated increased visibility and efficiency of the new regulatory scheme and increased awareness of the potential uses or medical benefits of marihuana, it can reasonably be expected that the numbers of applicants will increase significantly. As is the case with marihuana access programs operating in several of the States in the U.S., registration fees could eventually be imposed to recover some of the costs of administering these new Regulations in Canada. User fees, however, would not be instituted without a complete analysis of both the costs of delivering the program and the impact of fees on stakeholders.

Consultation

This regulatory framework was developed on the basis of consultation with stakeholders.

In response to requests from individual patients who requested access to marihuana for medical purposes, Health Canada, in consultation with health professionals and legal advisors, developed a process for exemptions for medical purposes under the authority provided in section 56 of the CDSA. The first exemption was issued in June 1999.

On October 6, 1999, Health Canada issued a *News Release, Update on Health Canada's initiatives on marijuana for medical and research purposes*. A specific commitment to public consultation was made in relation to the section 56 exemption program.

On February 28, 2000, a multi-stakeholder consultation workshop was held by Health Canada to:

- inform stakeholders of the current status of the section 56 exemption process, Health Canada's research plan for the medical use of marihuana, and activities undertaken related to the supply issue of research-grade marihuana;
- seek feedback from stakeholders on issues related to use of marihuana for medical purposes; and
- provide stakeholders with an opportunity to exchange views on issues related to the use of marihuana for medical purposes.

The following priority issues were identified by the workshop participants:

I. Obtaining a legal source of marihuana for section 56 exemptees;
II. Exemptions for caregivers;
III. Addressing the need for more information on the use of marihuana for medical purposes;
IV. Addressing concerns of law enforcement agencies;
V. Improvement of the process and tools for section 56 applications;
VI. Communications regarding section 56 process and Health Canada's activities regarding marihuana for medical purposes.

Input resulting from the February 2000 workshop has not only been used to refine the existing section 56 exemption process,

it has also provided an important basis for the development of the new regulatory approach. The workshop is therefore considered to have been very useful in terms of early consultation for the new framework.

While not a consultative process, the direction provided in the decision of the Court of Appeal for Ontario in the case of *R. v. Parker*, rendered on July 31, 2000, also provided valuable guidance for the development of a formal regulatory structure.

A *Notice of Intent* was published in *Canada Gazette Part I* on January 6, 2001, announcing Health Canada's intention to develop a regulatory approach for Canadians to access marihuana for medical purposes. Some comments were received as a result, which were considered in developing these Regulations.

Meetings were held with key stakeholders regarding the proposed regulatory scheme as part of the policy development process. These included meetings with representatives from the Canadian Medical Association, the Canadian Pharmacists Association, the Canadian AIDS Society, the RCMP, Solicitor General Canada, Department of Justice Canada, Correctional Service Canada, and the Canadian Association of Chiefs of Police.

The proposed Regulations were pre-published in *Canada Gazette Part I*, on April 7, 2001, followed by a 30-day comment period. Comments were received from 139 individuals and organizations. An analysis of the responses received indicates: 4% were fully supportive of the proposal; 42% were generally supportive and provided detailed constructive comments; 41% opposed the proposal and offered no constructive comments; and 14% were non-committal. It should be noted that 75% of those opposed to the regulatory proposal were supporters of the BC Marijuana Party. They faxed in form letters advocating the general legalization of marihuana for recreational and medical use, "without prior consent of any governing body." General legalization is, of course, outside the scope of this regulatory initiative.

Comments were received from two physicians, two medical associations and two provincial medical licensing authorities. Although a number of constructive comments were provided by these stakeholders, the medical associations and licensing

authorities oppose the use of smoked marihuana for medical purposes. Their reasons included: the lack of scientific evidence supporting its use; the fact that marihuana is not an approved drug product; the use of smoked marihuana is not an acceptable form of drug administration; and the responsibility on doctors to support the use of marihuana for medical purposes may place them in conflict with professional conduct rules relating to the use of unapproved or "alternative" medicines. The last point was also a concern expressed by many individuals.

Previous consultations and comments received from enforcement agencies have indicated that they seek clarity and recognize the need for the regulatory framework. Their ongoing concerns relate primarily to the ability of police officers to determine with certainty who does or does not possess the necessary authorization or licence, to avoid inappropriate and unnecessary enforcement activity.

Many comments were received from individual patients and patient-advocacy organizations. While a number of patients view these proposed Regulations as too restrictive, others complimented the Department on seriously addressing patient concerns. Their comments have been most useful in identifying areas where these proposed Regulations can be improved and identified other areas where ongoing consultations and refinements may be required. It is greatly appreciated that many seriously ill and disabled Canadians made the effort to participate in the development of the Regulations.

The following is a summary of the major issues identified from this consultation process, and Health Canada's response to the concerns expressed.

Issue #1: Categories of Medical Conditions or Symptoms

Concerns: Many patients felt that other medical conditions should be included in the Schedule of Category 2 illnesses. On the other hand, concerns were expressed by the medical community that there is insufficient scientific evidence to support the use of smoked marihuana in the treatment of any medical condition included in Category 2 and further suggested that Category 3 is much too broad.

Response: The decision as to which medical conditions would be included in Category 2 was made primarily on the basis of available scientific research. The broad wording of

Category 3 recognizes that there may be other conditions for which marihuana may provide medical benefit. Health Canada plans to review the list of Category 2 medical conditions on a regular basis, and will amend the Schedule as new information becomes available.

These Regulations are intended to provide access to marihuana for medical purposes, on compassionate grounds; this means that the use of marihuana, an unapproved drug in smoked form, should be considered for use in exceptional medical circumstances only. Category 1 includes terminal illnesses, which obviously meets this criterion and is supported by virtually all stakeholders. Category 2 includes a number of severe symptoms associated with specified serious medical conditions, where there is a reasonable amount of scientific evidence indicating that marihuana may provide symptomatic relief. Category 3, while difficult to precisely define within these Regulations, is intended to apply to severe symptoms. They include those in Category 2, but can be associated with other serious or life-threatening, chronic and severely debilitating, or complex and difficult to manage medical conditions for which compassionate access to marihuana may be justified. Providing access to marihuana for medical conditions that are outside the scope of the above-described categories is not the intended purpose of these Regulations.

Issue #2: Access to a Legal High-Quality Source of Marihuana

Concerns: Many individuals and organizations were concerned about patients' ability to grow marihuana on their own or, alternatively, to find someone with experience willing to help them by becoming a designated grower. In general, patients, advocacy groups, and some of the medical community strongly recommended that a safe, high-quality, controlled supply of marihuana be made available to patients to avoid the problems associated with growing by the patient, designated person, or unregulated distribution networks which are currently operating outside the law. Some problems that stakeholders mentioned associated with an unregulated supply include: a lack of experience in growing marihuana, leading to crop failures; product of unknown quality or potency; personal health, safety and security risks related to growing marihuana in one's home; and no access to safer alternatives to smoked marihuana.

Response: Health Canada acknowledges this problem and is attempting to deal with the issue. The Regulations address only personal possession and production because these are the most pressing issues. Options for the future production and distribution of a high-quality research or pharmaceutical grade marihuana are currently under consideration. This analysis must take into account a number of factors including Canada's commitments under international drug control conventions, as well as the *Food and Drug Regulations* that regulate the availability of drugs distributed in Canada.

Issue #3: Need for Further Research

Concerns: The medical community had serious concerns about the lack of evidence-based medical research on which to base their decisions. In particular, they were worried by the lack of information available to doctors about the dosage, strain, and potency levels best suited to their patients needs, as well as efficacy, possible drug interactions and long-term health effects. They were also concerned by current research which shows the harmful effects of smoking, in general, and smoking marihuana, in particular.

Response: Health Canada openly encourages research into new pharmaceutical uses of marihuana and is particularly interested in safer delivery systems. Until these products are available, along with more conclusive research on its positive and negative health effects, access to marihuana in crude smoked form is being granted only on compassionate grounds.

Issue #4: Patient vs. Practitioner Application

Concerns: Physicians, medical associations, medical licensing authorities, and other stakeholders felt that designating practitioners as responsible for completing and submitting the application on behalf of the patient created an unreasonable workload and would discourage them from participating. Further, individuals indicated they preferred to take charge of the application process themselves.

Response: The Regulations have been revised so that the application process for the authorization to possess and the licence to produce will be managed by the individual (patient) instead of the medical practitioner. The application must still include signed statements from the

practitioner(s), but the responsibility for the application will now lie with the individual. This revision will reduce the burden on physicians and enable patients to manage their own application process.

Issue #5: Restrictions on Growing Near Schools

Concerns: Individuals indicated that the one kilometre restriction on growing outdoors near schools and other places frequented by children was not feasible, necessary or reasonable.

Response: Health Canada agrees; it is unreasonable to expect either the individual to certify or for Health Canada to confirm the restriction. Also, the one kilometre restriction would likely prevent anyone from growing outdoors within an urban setting. The provision has been revised to be less restrictive and easier for all parties to assess. The revised provision prohibits growing marihuana outdoors immediately next to a school or similar public place a situation that would be unacceptable to the general public. Growers will also be encouraged to provide reasonable and meaningful security for outdoor plants, and to ensure that they are not visible to the public. It is in the best interests of the growers to prevent their plants from being lost or stolen to ensure the supply for medical use.

Issue #6: Number of Plants that may be Produced

Concerns: Individuals and organizations claiming experience in growing marihuana point out that the formula used to calculate the number of plants that may be grown is inappropriate. These parties cite the following variables as having an impact: different growing methods and conditions and the significant difference in yields between growing marihuana indoors and growing it outdoors. They claim such variables made it impractical to use the proposed formula to determine the number of plants, or the amount of marihuana that can be stored, under indoor and outdoor growing conditions. Some comments suggest that there is confusion about the amount of marihuana a person may possess under an authorization, versus the amount, stipulated in a personal production licence, that may be stored.

Response: Concerns about the differences between indoor and outdoor yields are supported by a review of independent sources of information. As a result, the number of plants

permitted under a personal licence to produce has been amended to reflect the different potential yields from indoor vs. outdoor cultivation. The formulas have been revised based on estimated yields per plant of 30 grams per plant grown indoors and 250 grams per plant grown outdoors. The maximum amount of dried usable marihuana that a licensed person may possess will continue to be calculated on the basis of 150% of amount produced, allowing for a reasonable amount of inventory to be on hand at the time newly harvested material is added to the inventory. It will be clearly explained in the guidance documentation being developed that the quantity of dried marihuana that an authorized person may possess (maximum 30 days supply) applies only where that person does not also hold a licence to produce (in which case the higher storage amount would apply) or when that authorized person is away from his/her usual place of residence, i.e. travelling. The 30-day supply for the authorized person should not be confused with the quantity that may be stored as stipulated in a personal production licence.

Issue #7: Transitional Provisions

Concerns: A number of individuals who have been granted exemptions under section 56 of the CDSA expressed concern about the absence of transitional provisions in the Regulations which would ensure they will be given a reasonable amount of time to comply with the new requirements. Many mentioned the possibility of a "grandfather clause" being implemented.

Response: Transitional provisions have been added to the Regulations that will effectively extend by an additional 180 days (6 months), all exemptions in effect at the time the Regulations come into force. Prior to the new expiry date, individuals will need to apply under other parts of the Regulations if they wish to continue to legally possess or produce marihuana for medical purposes. No new exemptions issued under section 56 of the CDSA providing access to marihuana for medical purposes will be granted once these Regulations come into force. Individuals and Health Canada will therefore have an additional 6 months to deal with this transition in a gradual and equitable manner. Extending existing exemptions by 6 months also brings them in line with the authorizations that will be issued under the regulatory scheme, which will be valid for one year.

Section 56 exemptees could, of course, apply under the new Regulations at any time before their exemption expires.

The coming into force date for these Regulations has been revised from July 15 to July 30, 2001, to allow the maximum amount of time for patients and physicians to become familiar with the new requirements following their final approval.

Issue #8: Criminal Record - Designated Person

Concerns: Both law-enforcement agencies and some individuals indicated that the requirement for a document proving that the proposed designated grower does not have a criminal record in another country was unreasonable and practically impossible to provide.

Response: The applicant for a designated-person production licence will not be required to submit a document proving that no foreign drug conviction exists, as it would place unreasonable demands on the applicant and the police. Instead, a statement from the proposed designated grower will be required. This statement does not need to include convictions relating to possession.

Issue #9: Inspection Provisions

Concerns: Individuals stated that the proposed provisions, providing for the potential inspection of marihuana-growing premises and records were too broad. In particular, the fact that marihuana is usually grown in private residences combined with the wide powers to search and seize contained in the Regulations was interpreted by many as an unwarranted invasion of privacy.

Response: Under the Regulations, inspectors will be able to conduct an inspection at a licensed production site only if consent is given by the occupant. Inspection provisions are generally deemed to be a necessary requirement for most regulatory schemes, particularly those involving licensing the production of a controlled substance. Furthermore, inspections are typically conducted to assess regulatory compliance. Health Canada appreciates the concerns of potential licence holders who will be growing within their own homes, and regular unannounced inspections are not contemplated. The inspection provisions provide an inspector with the authority to assess compliance with the Regulations. In addition, patients who hold personal-use

production licences will not be required to maintain records, in consideration of their medical condition. They are, however, encouraged to voluntarily maintain such records to the extent that they can.

Issue #10: Costs

Concerns: A large number of patients and health advocacy groups were concerned about the possibility that costs of administering this program might be passed on to the users. They pointed out that most of the patients are on fixed incomes because of their medical conditions and are already burdened with the costs of growing or purchasing marihuana. Also, some parties thought that marihuana costs should be covered by health insurance.

Response: Health Canada is sensitive to the financial situation of many patients who have serious illnesses. The related costs of delivering the authorization and licensing program will not, at least initially, be subject to user fees. As with any similar program, the costs will be reviewed in accordance with established government cost-recovery policies which ensure that the client's ability to pay is taken into consideration. The new regulatory scheme is anticipated to be less resource intensive than the existing exemption process with its high level of professional evaluation but the demand for service is expected to be greater in the future. In any case, no fees would be implemented without a thorough review and extensive consultation with affected parties. It should be noted that drug coverage by insurance plans is, in most instances, a provincial responsibility.

Issue #11: Legalization or Decriminalization

Concerns: There were several comments suggesting legalization or decriminalization, instead of limiting access to marihuana for medical purposes.

Response: The Regulations deal exclusively with the medical use of marihuana; therefore they do not address the issue of legalizing marihuana. Legalization and decriminalization arguments will be publicly debated by parliamentary committees over the next several months.

Issue #12: Compassion Clubs, Buyers Clubs and Cooperatives

Concerns: These organizations and some patients suggested the Regulations be revised to increase the number of

patients per grower, and to consider licencing “clubs” as an officially recognized distribution method. Reasons cited were “clubs’” expertise, prices charged, and the fact that they are already in the business of providing marihuana, although operating outside of the law.

Response: Health Canada is not prepared at this time to consider licensing other organizations or companies to produce and distribute marihuana. In December 2000, Health Canada issued a contract to a Canadian company to produce research-grade marihuana. Health Canada will be evaluating various options to ensure patients have access to a safe high-quality supply of marihuana for medical purposes.

Issue #13: Use of Photos - ID Cards

Concerns: Law-enforcement agencies suggested that photo identification cards be provided to all authorized individuals and all holders of production licences, including designated-person production licences. Several individuals questioned the provision that requires photos to be submitted along with the application as they saw it as a potential invasion of privacy and, in some cases, a question of personal dignity.

Response: Health Canada intends to provide secure photo identification cards to each individual who holds an authorization to possess or a licence to produce. It will be issued together with the authorization or licence documents containing the detailed information laid out in the Regulations. The identification cards will carry only the basic information required to identify the individual as a holder of an authorization and/or licence to produce and to show possession and production limits. No personal medical information will be indicated on the card. The detailed authorization and licence documents are to be stored at the location indicated on the form. The identification cards would be carried by individuals transporting marihuana either for personal use, in the case of the authorized person, or by the holder of a designated-person production licence, when transporting marihuana from the production site to the authorized person’s residence. The card can be shown to a police officer as evidence that the person is permitted to possess marihuana. In cases where police suspect a card has been tampered with, or is a false document, they can contact Health Canada to confirm the card’s authenticity. Card holders must take suitable

precautions to protect their cards from loss, since they could be misused by unauthorized persons.

Issue #14: Restrictions on Smoking or Use of Marihuana in General

Concerns: There were concerns expressed about where and when patients would be permitted to smoke marihuana for medical purposes. Specific concerns included: smoking in public places; second-hand smoke and drug exposure; driving while under the influence of marihuana; and the discretion left to institutions on whether they will allow the medical use of marihuana on their property.

Response: In general, how and where a patient may use a drug for medical use is not subject to federal regulation, but may be subject to the laws and policies of other levels of government. Smoking marihuana for medical purposes in a public setting, thereby potentially exposing others to the drug's effects, is unacceptable. Patients are therefore expected to use common sense when using this drug. The authorization simply allows possession, but does not give patients permission to use marihuana wherever or whenever he/she chooses the rights of others must also be considered. Hospitals and correctional institutions have their own regulations and policies governing the use of or access to drugs for medical use; these will determine whether marihuana may be used and under what conditions.

Similarly, while it is known that using marihuana influences a person's judgement and performance, and might impair his/her ability to drive, it is not clear how much a patient would need to use within a certain period to be impaired. Typically, approved drug products carry warnings or precautions related to driving or operating heavy machinery after using the drug. Since marihuana is not an approved drug in Canada, this warning will be provided by Health Canada to patients and health professionals in the guidance documents being prepared.

Since the Regulations do not regulate the actual use of the product, Health Canada does not propose to include mandatory restrictions relating to where or when marihuana may be used. These issues will, however, be monitored by Health Canada. Guidance documents provided to patients and practitioners will also include warnings about smoking in public places.

Issue #15: Reporting Professional Misconduct

Concern: The Canadian Medical Association was concerned by the broad discretion given to the Minister to report inconsistencies to professional licensing bodies. This concern relates to a lack of criteria by which the practitioner might be judged. Similarly, individuals expressed concern that physicians may fear censure by their colleges and be unnecessarily reluctant to support a patient's application for an authorization to possess marihuana.

Response: The provision in these Regulations is similar to that which exists in other controlled substances regulations. The provision allows Health Canada to share information with medical professional licensing authorities in rare circumstances. Health Canada recognizes the need to establish, in participation with the medical licensing authorities, reasonable standards or criteria for making this decision. This information will be communicated to patients and physicians.

Issue #16: Requirements of Specialists

Concerns: Many individuals and organizations expressed concern that Category 2's requirement that a medical specialist provide specific statements to support an application, and Category 3's requirement for statements from two specialists, make the process more restrictive than the current section 56 process. As well, many were concerned that people with legitimate medical needs would be denied, or at least have their applications delayed for months, because they did not have access to the required specialists. In particular, AIDS groups were concerned since there is no such thing as an AIDS specialist. Others were worried that the long wait to see a specialist could lead to discrimination against those in rural areas.

Response: Specialists play an important part in the diagnosis and treatment of any serious illness. As such, they have a role to play in supplying statements as part of the application process. The decision to support the use of marihuana to treat symptoms of a serious medical condition is not trivial. The fact that marihuana is an unapproved drug and is mainly ingested by smoking, makes the decision even more challenging.

Statements from one or more specialists required to support an application do not necessarily require the patient to visit the specialist in every instance. The primary physician may choose to consult with a specialist for this purpose, providing background on the file. Health Canada also recognizes that there may not be a specialty associated with every medical condition, and would therefore only expect that the specialty relate to some aspect of the condition being treated. The role and involvement of the specialist will be reviewed over time and clarified as necessary.

Issue #17: Information

Concerns: Individuals and health professionals had many questions about the proposed Regulations and expressed a strong interest in obtaining current reliable information, not only on the potential health benefits of marihuana, but on the health risks associated with using marihuana in smoked or other forms.

Response: Health Canada recognizes the need for a reliable and comprehensive source of information concerning marihuana so that patients, with the support of their physicians, can make informed health decisions. It is expected that Health Canada will play a lead role in facilitating the development of an information source whereby patients and health professionals can tap into the growing body of knowledge related to marihuana.

Comprehensive guidance documents are being developed to help patients and physicians understand the Regulations, and to guide them through the application process. It should be noted that “marihuana” is spelled with an “h” in the CDSA and its Regulations, as well as in the *Marihuana Medical Access Regulations*. “Marijuana” is the other common spelling both words mean “cannabis.” Either spelling is acceptable when used informally, however, in Canadian legislation and when referring to this legislation marihuana is spelled with an “h”.

As with all Regulations, analysis and consultation on a variety of issues will continue following implementation; as appropriate, any required regulatory amendments will be made in a timely manner. It is therefore Health Canada’s intention, upon final approval of the Regulations, to

communicate to stakeholders the results of the consultation process and to invite their ongoing participation in improving this regulatory scheme.

Finally, an informal electronic survey was conducted through Health Canada's electronic magazine beginning in August 2000. The following question was asked: "Let us know what you think about making marijuana available for medical purposes." Of the 146 comments received between September 2000 and May 2001, 104 agreed that marihuana should be available for medical purposes. Of this number, 40 respondents suggested the government should go further and consider legalizing marihuana. This forum will continue to be used to seek feedback on the Regulations and related topics.

Compliance and Enforcement

The Regulations include general provisions to conduct inspections relating to the production of marihuana. Health Canada inspectors will be authorized to examine inventories, records and security to ensure that marihuana production conforms with the Regulations. Inspections will take place only at the site where marihuana is produced under a licence, and only with the permission of the occupant. It is not anticipated that inspections would be frequent, regular or unannounced. Rather, they would be an infrequently used tool; for example, there could be inspections where unusually large quantities were being produced, where two or three licence holders were growing at a common site, or when there were complaints from members of the public.

Minimal record-keeping provisions exist relating to the production of marihuana by a licence holder. These records are to be shown to an inspector or submitted to the Minister upon request. Information contained in these records will be used to track production and consumption statistics as may be required to prepare reports to the UN.

Any activity that is not permitted under an authorization to possess or a licence to produce marihuana is potentially subject to police enforcement action. Complaints received concerning potential illegal activity may be shared with police agencies for enforcement purposes. For example, the production or storage of marihuana at premises or locations other than those authorized would be subject to enforcement

action. Trafficking, which includes, among other things, selling, giving, sending or delivering marihuana to any person not named in the authorization or licence, would also be subject to enforcement action.

Health Canada may also share information concerning any medical practitioner with the responsible provincial medical licensing authority on matters of professional conduct and medical practice or when required in the context of a lawful investigation conducted by the medical licensing authority.

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