Conroy & company

MEDICAL MARIJUANA

Health Canada

[14-1-o]

Marihuana Medical Access Regulations

Statutory Authority

Controlled Drugs and Substances Act

Sponsoring Department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

Description

The Marihuana Medical Access Regulations (the 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 in order 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 <Sign: Registered trademark>, which contains chemically synthesized THC; and CESAMET <Sign: Registered trademark>, 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 <Sign: Registered trademark> 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 cannabis users experience problems in controlling cannabis 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 remains 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.

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 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 over 180 exemptions allowing patients to possess and produce marihuana for their personal medical purposes have been granted. The proposed

Regulations will replace the current exemption process with a formal and more transparent process.

Proposed Regulatory Approach

Due to the health risks associated mainly with the smoked form and 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.

The proposed 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 minimum 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 have to be submitted by a medical practitioner on behalf of the patient. Depending on the category under which the application is being made, support from a medical specialist may be required. The proposed 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 proposed Regulations provide a less demanding process to obtain the authorization to possess because the risk of long term harm is not present. 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 found 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 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 have 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 may be submitted by a general practitioner, 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 may be submitted by a general practitioner, 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 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 the production of a maximum number of plants which will be specified in the licence. 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.

- Indoor or outdoor production will be permitted under the Regulations. The licence holder, whether the patient or his\her designated person, must take reasonable precautions to protect their 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 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.

There is one consequential regulatory amendment associated with this Regulatory Impact Analysis Statement (RIAS). This amendment makes minor modifications to the existing Narcotic Control Regulations to allow for the legal distribution of marihuana to individuals who hold an authorization to possess marihuana.

Alternatives

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 formal 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. This is mainly due to the fact 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. It is anticipated that the costs of administering the authorization program will, at some point, need to be recovered from the patients who receive the direct benefits of this program.

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 impacted by these Regulations. There will be some increase in administrative activity for medical practitioners resulting from the necessity for all authorization applications to be prepared and submitted by a medical practitioner on behalf of the patient.

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 impacted 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 impacted 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 that institution.

Researchers

These Regulations do not impact on 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 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 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 180 exemptions for medical purposes have currently 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 in several of the States in the U.S., registration fees may eventually need to be imposed to recover some of the costs of administering these new regulations.

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:

- Obtaining a legal source of marihuana for section 56 exemptees;

- Exemptions for caregivers;

- Addressing need for more information on the use of marihuana for medical purposes;

- Addressing concerns of law enforcement agencies;

- Improvement of the process and tools for section 56 applications;

- 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 the new 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 new regulatory approach for Canadians to access marihuana for medical purposes. Some comments have been received as a result, which will be considered in developing these Regulations.

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

Prepublication of proposed Regulations in Canada Gazette Part I will be followed by a 30 day consultation period. At this time, stakeholders will be advised through the usual channels of communication in addition to a public announcement. Comments received will be considered in finalizing these Regulations.

Guidance documents and information concerning the use of marihuana for medical purposes will be made available by Health Canada to assist medical practitioners, patients and enforcement authorities. Ongoing feedback from stakeholders will be used to improve the regulatory scheme.

Compliance and Enforcement

These Regulations include general provisions for inspection by Health Canada inspectors. Inspectors will be authorized to conduct inspections of inventories, records and security to ensure compliance with these Regulations.
Minimal record-keeping provisions exist relating to the production of marihuana by a licence holder. These records are to be 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 when required in the context of a lawful investigation conducted by the medical licensing authority.

Contact

Bruce Erickson, Office of Controlled Substances, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch, Address Locator: 3503D, Ottawa, Ontario K1A 1B9, (613) 957-2826 (Telephone), (613) 946-4224 (Facsimile), bruce_erickson@hc-sc.gc.ca (Electronic mail).

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 55(1) of the Controlled Drugs and Substances Act (<Reference a> S.C. 1996, c. 19), proposes to make the annexed Marihuana Medical Access Regulations.

Interested persons may make representations with respect to the proposed Regulations within 30 days after the date of publication of this notice. All such representations must cite the Canada Gazette, Part I, and the date of publication of this notice, and be addressed to Bruce Erickson, Office of Controlled Substances, Department of Health, Address Locator 3503D, Ottawa, Ontario K1A 1B9 (tel: (613) 957-2826; fax: (613) 946-4224; e-mail: Bruce_Erickson@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the Access to Information Act, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, April 5, 2001

RENNIE M. MARCOUX

Acting Assistant Clerk of the Privy Council

MARIHUANA MEDICAL ACCESS REGULATIONS

INTERPRETATION

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 5. (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 29, to produce marihuana for the applicant. (personne désignée)

"designated-person production licence" means a licence issued under section 31. (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 22. (licence de production à des fins personnelles)

"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)

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) An application for an authorization to possess dried marihuana for a medical purpose shall be made to the Minister by a medical practitioner on behalf of a patient.

(2) An application must contain the following information and statements:

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

(b) the full address of the place where the patient ordinarily resides as well as the patient'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 mentioned under paragraph (b) is an establishment that is not a private residence, the type and name of the establishment;

(e) the patient'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;

(f) the daily dosage of dried marihuana, in grams, and the form and route of administration, recommended by the medical practitioner;

(g) the period during which the authorization is needed, if less than 12 months;

(h) the medical practitioner's name, address, telephone number and provincial medical licence number and, if applicable, the medical practitioner's facsimile transmission number and e-mail address;

(i) a statement indicating that the authorization is sought in respect of marihuana either

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

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

(j) a statement, dated and signed by the medical practitioner, that the information submitted under paragraphs (e) to (h) is correct and complete.

(3) In the case of a category 1 symptom, the application must include a statement, dated and signed by the medical practitioner, certifying that the practitioner

(a) has determined that the patient suffers from a terminal illness;

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

(c) has determined that the recommended use of marihuana would mitigate the symptom;

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

(e) 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 2 symptom, the application must include a statement, dated and signed by a specialist, certifying that the specialist

(a) is a specialist in a specific area of medicine that involves treatment of the patient's medical condition;

(b) has determined that the patient suffers from the symptom identified under paragraph (2)(e) and that the symptom is associated with the medical condition or treatment identified under that paragraph;

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

(iii) the patient has experienced an adverse drug reaction to the drug used as a treatment, or there is a risk that the patient 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 patient, 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 patient;

(d) has determined that the recommended use of marihuana would mitigate the symptom;

(e) has determined that the benefits from the patient's recommended use of marihuana would outweigh any risks associated with that use, including risks associated with the long-term use of marihuana; and

(f) 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.

(5) In the case of a category 3 symptom, the application must include

(a) a statement, dated and signed by a specialist,

(i) certifying the matters referred to in subsection (4), and

(ii) listing all conventional treatments that have been tried or considered for the symptom and the reasons, from among those mentioned in paragraph (4)(c), why the specialist considers that those treatments are medically inappropriate; and

(b) a statement, dated and signed by a second specialist, certifying that the second specialist

(i) is a specialist in a specific area of medicine that involves treatment of the patient's medical condition,

(ii) is aware that the application is in relation to the mitigation of the symptom that is identified under paragraph (2)(e) and that the symptom is associated with the medical condition or treatment identified under that paragraph,

(iii) has reviewed the patient's medical file and the information provided under subparagraph (a)(ii) and has discussed the patient's case with the specialist providing that information and agrees with the certification made by the specialist under subparagraph (a)(i) with respect to the matters referred to in paragraphs (4)(d) and (e), and

(iv) 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.

(6) If the daily dosage recommended under paragraph (2)(f) is more than five grams, the medical practitioner providing the statement under subsection (3) or (4) or paragraph (5)(a) must also certify that

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

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

(7) The specialist must include their name, address, telephone number, provincial medical licence number and, if applicable, facsimile transmission number and e-mail address in the applicable statements under

(a) subsection (4) or paragraph (5)(a), unless the specialist is the medical practitioner making the application under subsection (1); or

(b) paragraph (5)(b).

(8) An application under this section must be accompanied by two copies of a current photograph clearly identifying the patient that

(a) shows a full front-view of the patient's head and shoulders and has a plain contrasting background;

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

(c) shows the patient's face unobscured by sunglasses or any other object; and

(d) on the reverse side, is certified by the medical practitioner making the application to be an accurate representation of the patient.

(9) An application under this section must include a statement, signed and dated by the patient, certifying that

(a) the information submitted under paragraphs (2)(a) to (d) and (i) is correct and complete;

(b) the patient 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, and understands the significance of this fact; and

(c) the patient has discussed with the medical practitioner making the application the risks of using marihuana, and consents to using it for the recommended medical purpose.

Issuance of Authorization to Possess

5. (1) Subject to section 6, if an application complies with section 4, the Minister shall issue to the patient an authorization to possess for the medical purpose mentioned in the application, and shall provide to the medical practitioner who made the application notice of the authorization.

(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 14(1) or 16(3) is the amount determined according to the following calculation:

A multiplied by 30

where A is the daily dosage of dried marihuana recommended for the holder under paragraph 4(2)(f), 13(1)(c) or 16(2)(b), whichever applies.

Grounds for Refusal

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

(a) the patient 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 4(4)(c); 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 patient in writing of the reason for the proposed refusal; and

(b) give the patient an opportunity to be heard.

Expiry of Authorization

7. An authorization to possess expires 12 months after its date of issue or, if a shorter period is specified under paragraph 4(2)(g), at the end of that period.

Application for Renewal of Authorization to Possess

8. (1) An application to renew an authorization to possess shall be made to the Minister by a medical practitioner and must include

(a) the number of the authorization; and

(b) the information, statements and any other item required under section 4, excluding the statement of the second specialist referred to in paragraph 4(5)(b) in the case of a category 3 symptom.

(2) For the purpose of paragraph (1)(b), a photograph referred to in subsection 4(8) is required only with every second renewal application.

9. 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 a category 1 symptom is made for the person who was the holder of the expired authorization, the new application shall be considered to be an application to renew the expired authorization.

10. 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 under category 2 or 3, whichever applies.

11. Subject to section 12, if an application complies with section 8, the Minister shall renew the authorization for the medical purpose mentioned in the application.

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

(a) for any reason referred to in section 6; 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.

Application to Amend Authorization to Possess

13. (1) An application to amend an authorization to possess shall be made to the Minister by the medical practitioner 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) a recommended daily dosage of dried marihuana, if the new dosage is in excess of five grams.

(2) The application must indicate

(a) the number of the authorization;

(b) the requested amendment and supporting reasons; and

(c) the information and statements required under section 4.

14. (1) Subject to section 15, if an application complies with section 13, the Minister

shall allow the amendment.

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

15. The Minister shall refuse to amend an authorization to possess for any reason referred to in subsection 6(1).

Notice of Change of Information

16. (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 4(2)(f), if the new dosage is not in excess of five grams.

(2) The notice of change must be accompanied by

(a) in the case of a change under paragraph (1)(a) or (b), proof of the change;

(b) in the case of a change under paragraph (1)(c), a statement, dated and signed by the medical practitioner for 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, 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 Minister amends an authorization to possess under subsection (3) with respect to the name or address of the holder of the authorization, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization.

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

Providing Assistance to Holder

17. While providing assistance in the administration of marihuana to the holder of an authorization to possess, 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

18. 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

19. (1) 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 53(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

20. (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 is a person for whom an application for an authorization to possess either has previously been made or is made at the same time as the application for the licence.

(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

21. (1) An application for a personal-use production licence shall be made to the Minister by a person referred to in subsection 20(1) and must contain

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

(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) the name of the medical practitioner who made or is making an application for an authorization to possess for the applicant;

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

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

(g) if it is proposed to produce marihuana outdoors, a statement whether the production site is located within one kilometre of a school, public playground, day care facility or other public place frequented mainly by persons under 18 years of age;

(h) if the proposed production site is not the ordinary residence of the applicant and is not owned by the applicant, a statement, dated and signed by the owner of the site, consenting to the production of marihuana at the site;

(i) a statement that the dried marihuana will be kept indoors and indicating which of the following is proposed as the site where the dried marihuana may be kept:

(i) the proposed production site, or

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

(j) a description of the security measures that will be implemented at the proposed production site and the proposed site where dried marihuana may be kept; and

(k) a statement, dated and signed by the applicant, certifying that the information provided in the application is correct and complete.

(2) An application under subsection (1) may not be made jointly with another person.

Issuance of Licence

22. (1) Subject to section 24, if an application complies with section 21, 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 maximum number of marihuana plants that may be under production at the production site at any time;

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

(g) the maximum quantity of dried marihuana that may be kept at the site authorized under (f) at any time;

(h) the date of issue; and

(i) the date of expiry.

Maximum Number of Plants and Quantity of Marihuana

23. (1) The maximum number of marihuana plants referred to in subsections 14(2) and 16(5) and paragraphs 22(2)(e) and 31(2)(f) is the number determined according to the following calculation:

(B multiplied by 365) divided by (45 multiplied by 4)

where B is the daily dosage of dried marihuana, in grams, recommended for the applicant under paragraph 4(2)(f), 13(1)(c) or 16(2)(b), whichever applies.

(2) If the number determined under subsection (1) is not a whole number, it shall be rounded to the next-highest whole number.

(3) The maximum quantity of dried marihuana referred to in subsections 14(2) and 16(5) and paragraphs 22(2)(g) and 31(2)(h) is the amount determined according to the following calculation:

C multiplied by 45 multiplied by 1.5

where C is the maximum number of marihuana plants, as determined in accordance with subsection (1), that the holder of the licence is authorized to produce.

Grounds for Refusal

24. 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 19;

(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;

(e) the applicant would be the holder of more than one licence to produce; or

(f) it is proposed to produce marihuana outdoors and the production site is located within one kilometre of a school, public playground, day care facility or other public place frequented mainly by persons under 18 years of age.

Expiry of Licence

25. 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

26. (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

27. 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

28. (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 is a person for whom an application for an authorization to possess either has previously been made or is made at the same time as the application for a designated-person production licence.

(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

29. (1) An application for a designated-person production licence shall be made to the Minister by a person referred to in subsection 28(1), and must contain

(a) the information referred to in paragraphs 21(1)(a) to (e) and the statement referred to in paragraph 21(1)(k);

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

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

(2) An application referred to in subsection (1) may not be made jointly with another person.

Accompanying Documents

30. An application for a designated-person production licence must be accompanied by

(a) a statement, by the designated person,

(i) providing the information required under paragraphs 21(1)(f), (g) and (j),

(ii) that the dried marihuana will be kept indoors and indicating which of the following is proposed as the site where the dried marihuana may be kept:

(A) the proposed production site, or

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

(iii) certifying that the information provided under this section and paragraphs 29(1)(b) to (d) is correct and complete;

(b) if the proposed production site is not the ordinary residence of the applicant or the designated person and is not owned by either, a statement, dated and signed by the owner of the site, consenting to the production of marihuana at the site; and

(c) 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

(i) a designated drug offence, or

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

Issuance of Licence

31. (1) Subject to section 32, if an application complies with sections 29 and 30, 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 designated person 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 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 that may be kept at the site authorized under paragraph (g) at any time;

(i) the date of issue; and

(j) the date of expiry.

Grounds for Refusal

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

(a) if the designated person is not eligible under section 27; or

(b) for any reason referred to in section 24.

Expiry of Licence

33. 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

34. 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 number of the licence; and

(b) the information, statements and any other item required under subsection 21(1) or under subsection 29(1) and section 30, whichever apply.

35. Subject to section 36, if an application complies with section 34, the Minister shall renew the licence to produce.

36. The Minister shall refuse an application to renew a licence to produce for any reason referred to in section 24 or 32, whichever applies.

Change of Production Site

37. (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.

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

(a) the number of the licence;

(b) the full address of the proposed production site and supporting reasons for the proposed change of site; and

(c) the information, statements and any other item required under subsection 21 or subsection 29(1) and section 30, whichever apply.

38. Subject to section 39, if an application complies with subsection 37(2), the Minister shall amend the licence to produce.

39. The Minister shall refuse to amend a licence to produce for any reason referred to in section 24 or 32, whichever applies.

Change of Site Where Dried Marihuana Is Kept

40. (1) If the holder intends to change 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) An application under subsection (1) shall state

(a) the new site, selected from among those permitted under paragraph 21(1)(i) or subparagraph 30(a)(ii), 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

41. (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 37.

(3) A notice under paragraph (1)(a) or (b) 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

42. (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

43. The holder of a licence to produce may produce marihuana indoors or outdoors but only at the production site mentioned in the licence.

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

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

Records

46. (1) The holder of a licence to produce must, at either the production site or the site where dried marihuana may be kept, maintain records of the following information:

(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 licence to produce must provide the Minister with a copy of any record referred to in subsection (1).

Inspection

47. (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 a 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 this 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

48. (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

49. 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

50. (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

51. (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

52. (1) On request by the holder of an authorization to possess, the Minister shall revoke the authorization and any licence to produce issued on the basis of the authorization.

(2) Subject to section 54, 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 subsection 4(8) or section 8 as part of the application for the authorization or renewal is not an accurate representation of the holder of the authorization.

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

(2) Subject to section 54, the Minister shall revoke a licence to produce if

(a) the holder is not eligible under section 19 or 27, 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; or

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

54. The Minister shall not revoke an authorization to possess or a licence to produce under section 52 or 53 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

55. (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 56, 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.

56. (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.

Complaints and Disclosure of Information

57. (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.

58. 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 states

(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.

NARCOTIC CONTROL REGULATIONS

59. The portion of paragraph 3(1)(d) (<Reference 1> SOR/85-930) of the Narcotic

Control Regulations (<Reference 2> C.R.C., c. 1041) before subparagraph (i) is replaced by the following:

(d) has obtained the narcotic, other than Diacetylmorphine (heroin) or Cannabis (marihuana), for his own use

60. (1) The portion of subsection 53(2) (<Reference 1> SOR/85-930) of the Regulations before paragraph (a) is replaced by the following:

(2) Subject to subsections (3) and (4), a practitioner may administer, prescribe, give, sell or furnish a narcotic, other than Cannabis (marihuana), to a person or animal if

(2) Section 53 of the Regulations is amended by adding the following after subsection (2):

(2.1) A practitioner may sell or furnish Cannabis (marihuana) to the holder of an authorization to possess issued under the Marihuana Medical Access Regulations if the practitioner has obtained the marihuana from a licensed dealer under subsection 24(2) of these Regulations.

COMING INTO FORCE

61. These Regulations come into force on July 15, 2001.

SCHEDULE (Section 1)

CATEGORY 2 SYMPTOMS

*** TABLE EXTRACTED ***