Vol. 138, No. 43 — October 23, 2004

Regulations Amending the Marihuana Medical Access Regulations

Statutory authority

Controlled Drugs and Substances Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Description

The main objective of this initiative, undertaken by Health Canada, is to respond to concerns expressed by the stakeholders in the medical marihuana program by

- streamlining the regulatory requirements and processes associated with applying for an authorization to possess marihuana for medical purposes under the *Marihuana Medical Access Regulations* (MMAR);

- enabling Canadian police to access the information they need in order to prevent unnecessary law enforcement action being taken; and

- moving the provision of marihuana for medical purposes in Canada toward a more traditional health care model.

In presentations to Health Canada, patients have characterized MMAR requirements and processes for obtaining an authorization to possess marihuana as onerous and, therefore, an impediment to access. Similar arguments have been made to Canadian Courts in cases that have challenged the constitutionality of the MMAR.

Physicians have expressed concern that, under the MMAR, they have been assigned a 'gatekeeper' role that they find difficult to fulfil due to the lack of scientific information available concerning the use of marihuana for specific medical purposes. Such information, physicians point out, is necessary for them to support a patient's application for authorization to possess marihuana,

particularly if they are to provide the currently required information on benefits, risks, dosage, and form and route of administration.

Physicians have also noted that the MMAR may have created an expectation that all physicians should support the use of marihuana for medical purposes. Although it remains within the professional purview of a physician to recommend against a patient's use of any particular drug therapy, such an expectation has the potential to strain the physician-patient relationship should a physician opt not to support a patient's application under the MMAR.

Police have emphasized that they must be able to confirm with Health Canada whether named individuals are authorized to possess or produce marihuana, and whether specified locations are the sites of licensed marihuana production activities. Police point out that authorized and licensed persons, police and others in the community may be exposed to unnecessary risks if police are not able to distinguish between persons who are acting within the law and those engaged in illegal activities related to marihuana.

The proposed regulatory amendments streamline the application and renewal processes for authorizations to possess, and provide explicit authority for Health Canada to communicate information to police under prescribed circumstances. In addition, the amendments provide limited authority for pharmacists to supply marihuana to authorized persons and will clarify other provisions of the MMAR.

These amendments maintain an appropriate balance between providing seriously ill persons with compassionate access to marihuana, on the one hand, and the need to regulate marihuana—a controlled substance and an unapproved drug product—on the other.

The policy and legislative framework: Medical marihuana program

Health Canada's medical marihuana program is built on three pillars:

- defining the regulatory framework to permit persons to possess and produce marihuana for medical purposes;

- fostering research into the safety and efficacy of marihuana when used for specific medical purposes; and

- establishing a safe, reliable, legal source of marihuana for medical purposes in Canada.

Health Canada's medical marihuana program provides a compassionate approach to Canadians who suffer from serious medical conditions; the program does not deal with the use of marihuana for non-medical purposes.

The MMAR, which came into force on July 30, 2001, provide the regulatory framework under which seriously ill persons can obtain an authorization to possess marihuana for their own medical purposes. An authorization to possess is issued to an applicant only once the applicant has consulted with a physician who has confirmed both the applicant's medical condition and that conventional treatments have been tried by, or considered for, the applicant.

As of July 2, 2004, 781 persons in Canada are allowed to possess marihuana for medical purposes. Within that group, 491 persons are also authorized to produce marihuana for themselves, while 81 others have obtained authority for a designated person to produce it on their behalf.

To enhance protection of the health and safety of Canadians, Health Canada's strategic direction for the medical marihuana program envisions the program taking on, to the extent possible, the features of the traditional health care model employed for other medicinal agents available in Canada. Such a model would include

- continued support for research and enrolment of patients in clinical or open label trials as the first consideration of patients and physicians;

- a centralized source of marihuana that complies with product standards, accompanied in the longer term by a phase-out of personal cultivation;

- distribution of marihuana for medical purposes to authorized persons through pharmacies;

- updated information stemming from research into the risks and benefits of marihuana when used for medical purposes, and education of patients and physicians; and

- improved post-market surveillance to monitor the safety and efficacy of marihuana when used for medical purposes.

This strategic direction guided the development of the December 2003 amendments to the MMAR, as well as the currently proposed amendments.

Amendments to the MMAR

The first phase of amendments to the MMAR was completed in December 2003. It focused largely on issues related to the source and supply of marihuana for medical purposes, and responded to the October 7, 2003, Ontario Court of Appeal decision in *Hitzig et al. v. Her Majesty the Queen*.

This second phase of proposed amendments is based on a broader review of the MMAR to address issues expressed by Health Canada's stakeholders in the

medical marihuana program and involved a comprehensive consultative process. The following provides a description of the proposed Phase 2 amendments to the MMAR:

Application for an authorization to possess marihuana for medical purposes

The number of categories of symptoms under which a person may apply for authorization to possess marihuana for medical purposes is reduced from three to two. The previous Categories 1 and 2 are merged into one category (Category 1). The need for a specialist to sign the medical declaration for the symptoms set out in the Schedule to the Regulations (previous Category 2) has been eliminated. While assessment of the applicant by a specialist is still a requirement under the new Category 2, the treating physician, whether a specialist or not, can sign the medical declaration.

Both the Applicant's Declaration and the Medical Declaration required as part of an application for an authorization to possess are revised. Applicants are now asked to acknowledge and declare their acceptance of the risks associated with the use of marihuana for medical purposes in their declaration.

Physicians are no longer required, in their declarations, to make definitive statements regarding benefits outweighing risks, or to make specific recommendations regarding the daily dosage of marihuana to be used by the applicant. In addition, the information that the physician is required to provide in the medical declaration has been reduced to only those elements essential to confirm that the applicant suffers from a serious medical condition and that conventional treatments are inappropriate or ineffective. For example, physicians are no longer required to list conventional therapies that have been tried or considered, or to provide their reasons for finding those therapies to be ineffective or inappropriate.

Streamlining the application, renewal and amendment processes for an authorization to possess

The above-cited amendments serve to streamline MMAR application and renewal processes. In addition, the requirement for authorized persons to submit a new photograph for identification purposes with every second renewal, has been changed to every fifth renewal. MMAR requirements related to notifying Health Canada of changes, and to applying for amendments to an authorization have also been streamlined.

Requirements for expired authorization and licence documents to be returned to Health Canada have been eliminated. Authorization and licence documents must still be returned, however, if amended documents are issued, or if the authorization or licence is revoked.

Designated persons sending dried marihuana

The provisions of the MMAR governing the method by which a designated person can send dried marihuana to the authorized person for whom they are licensed to produce are amended to remove a potential impediment to access for authorized persons.

Authority to communicate information to Canadian police

These amendments provide Health Canada with explicit authority to communicate limited authorization and licence information to Canadian police in response to a request received from Canadian police in the context of an investigation under the *Controlled Drugs and Substances Act* or the MMAR.

Authority for provision of marihuana through pharmacies

These amendments provide limited authority for a pharmacy-based distribution system for dried marihuana that is produced by a licensed dealer on contract with Her Majesty in right of Canada, to authorized persons without a prescription from a physician. This will allow the conduct of a pilot project to assess the feasibility of distributing marihuana for medical purposes through the conventional pharmacy-based drug distribution system.

Information included on an authorization to possess

Information regarding an authorized person's medical condition will no longer appear on authorization documents issued under MMAR section 11. This will provide added privacy protection should authorized persons be required to show their authorization documents as proof of their authority.

The name of the physician who signed the medical declaration will be added to the information that will be included on the letter of authorization. This information will, however, not be included on the photo identification card issued to authorized persons as proof of their authority. A letter of authorization to possess will now contain essentially the same information as found on a prescription from a physician authorizing a pharmacist to dispense a controlled substance. Accordingly, the holder of an authorization to possess may, at some time in the future, be able to present their authorization to a pharmacist in order to obtain dried marihuana, without first obtaining a prescription from their physician.

Clarification of existing provisions

Paragraph 10(*d*) of the MMAR has been amended to make clear that the photograph of the applicant required as part of an application for authorization to possess is to be certified by the same physician who signs the medical declaration.

Section 23 of the MMAR has been amended to clarify the maximum quantity of dried marihuana that a care giver may possess while in the presence of, and providing assistance to an authorized person.

Paragraph 34(1.1)(*a*) of the MMAR has been amended to clarify the interpretation of "securely pack" for purposes of shipment of marihuana from the holder of a designated-person production licence to the person authorized to possess.

Subparagraph 34(1.1)(*b*)(ii) of the MMAR has been amended to clarify the original intent of the provision: to improve access to marihuana for medical purposes for persons authorized to possess under the MMAR and to provide for a safe, secure "method of sending."

Section 59 of the MMAR has been amended to make clear that the prohibition on altering an authorization to possess or licence to produce applies to any documents issued to the holder as proof of their authorization or licence, including the photo identification card.

Consequential and technical amendments

A number of other MMAR provisions have been amended to ensure consistent use of terminology throughout the Regulations, and to update cross-references between provisions required as a result of renumbering of new or amended provisions. In addition, all provisions related to authorities to supply marihuana seeds or dried marihuana have been re-organized into Part IV of the Regulations.

Alternatives

The challenge in amending the MMAR is to maintain an appropriate balance between the often divergent concerns of different stakeholders and adequate regulatory control. A number of alternatives were considered for each substantive amendment. However, in order for an alternative to be considered viable, it was necessary that it fit within the following parameters, as set out by the Department:

- Marihuana will be accessible on compassionate grounds and its use will be regulated.

- The Government of Canada will continue to respect the international drug control conventions to which Canada is a Party. These conventions include the requirement for a government agency to have exclusive rights over importing, exporting, selling, and maintaining stocks of marihuana. This means that Health Canada will limit and maintain tight control on marihuana production.

• Marihuana is a drug as defined by the *Food and Drugs Act* and is not a natural health product as defined by the *Natural Health Products Regulations*.

• Health Canada will continue to require the opinion and support of a physician, since physicians are the professionals best positioned to assess medical need. Decisions by the courts have lent support to the continued involvement of physicians, including specialists.

• Authorized persons will have access to a legal, standardized, quality-controlled source of marihuana.

Amendments have been made to other provisions of the MMAR in the interests of consistency, clarifying regulatory requirements, and streamlining the application and renewal processes, wherever possible.

Application for an authorization to possess marihuana for medical purposes

1. Status quo

Patients and physicians find the MMAR requirements and processes for obtaining an authorization to possess onerous. Physicians have indicated that it is difficult to provide all of the information required on the medical declaration (e.g. to document all other treatments that have been tried or considered) and to make definitive statements regarding the risks, benefits, dosage, and form and route of administration associated with the use of marihuana, particularly given the lack of adequate scientific information about the use of marihuana for specific medical purposes. As a result, physicians are generally uncomfortable with signing the medical declarations, and some are reluctant to support a patient's application.

Patients have raised concerns about the need to obtain a signed medical declaration from a specialist for Categories 2 and 3 and the difficulty encountered in accessing specialists, particularly for those patients who live outside of large metropolitan areas. In regards to the specialist requirement, physicians have commented that this requirement may not give due recognition to the level of knowledge and expertise that may be possessed by physicians who have chosen not to pursue accreditation as a specialist.

In light of the general level of dissatisfaction with the current framework, the status quo is unacceptable.

2. One category, no specialists required

In this alternative, there is only one category of symptoms under which a person may apply for an authorization to possess marihuana for medical purposes. The

same level of medical scrutiny is applied to all applications for authorization to possess. The requirements for specialist involvement are eliminated.

Some stakeholders indicated that naturopaths or herbalists should also be permitted to sign the medical declaration in support of an application. However, marihuana is a controlled substance under the *Controlled Drugs and Substances Act*. With few exceptions, controlled substances can be sold or provided to a patient only by, or under the direction of a physician, dentist or veterinarian.

It is clear that there is more scientific information available concerning the use of marihuana to treat some symptoms, than there is for others. A scheme that accepts the same level of medical assessment for all symptoms would not be reflective of the existing state of scientific knowledge concerning the use of marihuana for medical purposes and the different combinations of benefits and risks associated with that use.

This alternative is rejected on the basis that it fails to provide adequate regulatory control over an unapproved, controlled substance, and fails to provide a balanced response to the concerns of stakeholders.

3. Two categories, amended declarations [the recommended alternative]

This alternative reduces the number of categories of symptoms under which a person may apply for an authorization to possess marihuana for medical purposes from three to two. The distinction between the two categories is based largely on the scientific information available regarding the use of marihuana for specific medical purposes, and accordingly on the level of medical scrutiny required in support of an application.

The new Category 1 merges the previous Category 1 and Category 2 symptoms and is comprised of

- any symptom treated within the context of providing compassionate end-of-life care (previously defined as a symptom associated with a terminal illness for which the prognosis was death within 12 months); or

- the symptoms associated with the specified medical conditions listed in the Schedule to the Regulations. (The Schedule is to be updated periodically, based on a review of emerging scientific evidence and the recommendations of a panel of experts.)

In Category 1, either an applicant's medical condition, or the available scientific information on the applicant's medical symptom(s) and condition(s) make the requirement for a specialist to support the application unnecessary. It is recognized, however, that in many Category 1 cases a specialist will have been consulted.

Category 2 now includes any debilitating symptom of a medical condition other than those in Category 1. Under Category 2, persons with debilitating symptoms can apply to obtain an authorization to possess marihuana for medical purposes, if a specialist confirms the diagnosis and that conventional therapies are inappropriate or ineffective for the treatment of that patient's symptom(s).

While an assessment of the applicant's case by a specialist is required, the treating physician, whether or not a specialist, can sign the medical declaration, thereby eliminating the need for an applicant to see a specialist for the sole purpose of having the medical declaration signed.

Under this alternative, the applicant's declaration and the medical declaration are amended to respond to the concerns raised by patients and physicians and better reflect the information currently available with respect to the benefits and risks of marihuana when used for medical purposes. Statements regarding the amount of dried marihuana to be used by an authorized person, if in excess of five grams per day, have been moved from the medical declaration to the applicant's declaration. The declarations required for both categories are essentially the same.

In the revised medical declaration, the treating physician is required to provide

- information about the applicant's medical condition;

- summary statements regarding other therapies that have been tried or considered for the applicant; and

- the amount, and form and route of administration of marihuana that the applicant intends to use.

The physician is no longer required to transcribe information from the patient's medical record into the medical declaration in order to demonstrate that all conventional treatments that have been tried or considered are inappropriate or ineffective.

These amendments more closely align the statements made in the medical declaration with the level of scientific evidence available concerning the use of marihuana for medical purposes and reduce the time required for physicians to complete the medical declaration.

The new applicant declaration requires the applicant to confirm that potential risks and benefits associated with the use of marihuana have been discussed with the physician making the medical declaration. The applicant must also acknowledge and accept those risks in the declaration to demonstrate that the risks were considered in the applicant's decision regarding the use of marihuana for medical purposes.

These amendments establish between the applicant and the physician a more appropriate sharing of responsibility for the decision to use marihuana as an alternative treatment.

An authorization to possess will continue to be valid for one year, which is consistent with the maximum period a prescription is generally valid before an authorized person is required to re-visit a physician.

In addition to the above, this alternative is accompanied by an administrative change that allows for an abbreviated application for renewal. When applying to renew an authorization to possess, if there is no change to the information provided in the previous application or request for amendment, the applicant and physician will no longer be required to resubmit all of the information in the application form. A signed declaration from the applicant and physician stating that there has been no change to the information previously provided, will be sufficient.

Designated persons sending dried marihuana

1. Status quo

The MMAR require designated persons, when sending dried marihuana to the authorized person for whom they are licensed to produce, to use a method of sending that involves "obtaining a signed acknowledgment of receipt from the holder of the authorization to possess." Although national couriers and common carriers offer product lines and services that involve signature confirmation of delivery, there are no delivery services typically offered to the general public that restrict confirmation of delivery to a single, named individual. It is, therefore, not reasonably practicable for a designated person to comply with the regulatory requirement to use a method of sending that involves "obtaining a signed acknowledgment of receipt by the holder of the authorization to possess."

When this particular provision of the MMAR came into force in December 2003, it was part of a package of amendments intended to improve access to marihuana for medical purposes for persons authorized to possess under the MMAR, allowing designated persons to send, rather than hand deliver, dried marihuana to the authorized person for whom they are licensed to produce. The current wording of subparagraph 34(1.1)(*b*)(ii) does not comport with this original intent.

Accordingly, the status quo is rejected.

2. Allow persons other than the authorized person to sign acknowledging receipt of the package sent by the designated person [the recommended alternative]

In this alternative, the MMAR is amended to remove the stipulation that signed acknowledgment of receipt of the package of dried marihuana sent by the

designated person must be obtained from the holder of the authorization to possess. This change allows designated persons to choose a method of sending that involves a courier company or a common carrier (e.g. Canada Post), while retaining the requirement for obtaining a signed acknowledgment of receipt at the destination.

With this amendment, a potential impediment to access is removed.

Authority to communicate information to Canadian police

1. Status quo

Under the present system, Health Canada does not normally communicate authorization or licence information to police, unless the holder of the authorization or licence has consented to the disclosure. Exceptions to this practice would include situations wherein Health Canada is served with a search warrant requiring disclosure of specific information.

Although authorized and licensed persons are currently required under the Regulations to show proof of their authority to the police on demand, the police have cited examples where unnecessary investigation and enforcement actions could have been avoided by access to authorization and licence information prior to action being taken.

As of July 2004, between 25 percent and 30 percent of persons authorized or licensed under the Regulations have not given their consent for Health Canada to communicate their information to Canadian police. Police point out that this is both problematic and of significant concern to them given that across Canada, they are striving to cope with increasing numbers of illegal marihuana grow operations.

Police would like to be able to focus their limited resources on illegal activities involving marihuana, rather than on the activities of authorized and licensed persons who are operating within the law. Of particular concern to police and Health Canada is that unnecessary police entry into a dwelling could put the safety of authorized and licensed persons, police, and others in the community at risk.

Given the negative impact on law enforcement and the risks to public safety, the status quo is rejected.

2. Provide regulatory authority for the Minister to communicate limited information to Canadian police [the recommended alternative]

In this alternative, Health Canada does not ask for the consent of authorized and licensed persons before communicating limited information, as defined in the

Regulations, to Canadian police. The information to be communicated is provided only in response to a request made by Canadian police engaged in an investigation under the *Controlled Drugs and Substances Act* or the MMAR.

The police are not given access to Health Canada's complete database of information regarding authorized and licensed persons. Rather, the information that is subject to disclosure is limited to what the police require to confirm whether the activities of a named individual or at a specified address are associated with an authorization or licence issued under the MMAR.

Information to be provided to Canadian police is that which is included on the authorized or licensed person's photo identification card. An authorized person's medical information is not, under any circumstances, included in what can be disclosed.

This alternative, the recommended alternative, responds to the concerns of Canadian police, while also addressing the privacy concerns of other stakeholders regarding communication of information to the police.

Provision of marihuana through pharmacies

1. Status quo

Medical organizations are generally discouraging their members from prescribing marihuana until a Notice of Compliance is issued regarding the safety, efficacy and quality of marihuana when used for medical purposes. There is currently no authority under the *Narcotic Control Regulations* or the MMAR that would allow an authorized person to obtain marihuana from a pharmacist without a written prescription from a physician. Without the appropriate authority in legislation, Health Canada cannot take steps to explore the feasibility of distributing marihuana through pharmacies—a key element in Health Canada's vision for moving the program toward a traditional health care model.

The status quo is therefore rejected.

2. Provide authority for distribution of marihuana through pharmacies [the recommended alternative]

Using a pharmacy-based distribution system for drugs is an important element of the Canadian health care model. Pharmacists complement the role of physicians by providing additional information to both the authorized person and the physician and closer monitoring of a patient's drug therapy between visits to the physician.

While physicians are already involved in the authorization process, involving pharmacists in the distribution system could enhance the identification and

mitigation of risks to the authorized person, particularly when marihuana is combined with other drug therapies the authorized person may be using. A pharmacy-based distribution system for marihuana for medical purposes has been in place in the Netherlands since September 2003.

Stakeholders have expressed strong support for the conduct of a pilot project to assess the feasibility of distributing marihuana for medical purposes through a pharmacy-based system. This alternative provides the authority to enable such a pilot project to take place.

Health Canada intends to work with pharmacists and their associations and regulatory authorities to develop a protocol for the conduct of a pilot project. If the feasibility of a pharmacy-based distribution system is confirmed, the regulatory framework will be enhanced to include provisions comparable to those found in the *Narcotic Control Regulations* governing the distribution of other controlled drugs through pharmacies.

Amendment of provincial regulations related to pharmacy distribution may also be required to allow for the distribution of marihuana to authorized persons without a physician's prescription.

Benefits and costs

These regulatory amendments are expected to impact the following sectors:

Holders of authorizations to possess and licences to produce

New applicants and those already authorized to possess marihuana for medical purposes will benefit from facilitated access to marihuana for medical purposes as a consequence of the streamlined application and renewal processes. While an appropriate level of medical scrutiny is maintained to protect the health and safety of authorized persons, the requirements for specialist involvement in the application process are reduced. The indirect cost to applicants associated with the time and travel to see specialists will be reduced accordingly.

The new provisions allowing Health Canada to communicate limited authorization or licence information to Canadian police will benefit authorized and licensed persons insofar as their exposure to risks associated with unnecessary law enforcement action will be reduced.

Communication of information to police without explicit consent from authorized and licensed persons may be perceived as a loss of privacy. However, the potential loss of privacy is offset by the greater social good that will be derived from confirming necessary information for police.

The amendment allowing for the signed acknowledgment of receipt of a package of dried marihuana to be obtained from a person at the destination who may or may not be the authorized person removes a potential and unintended impediment to access for authorized persons and enables the designated person to fully comply with the prescribed conditions for sending, without having to take exceptional steps to do so. Not only does this change facilitate sending by the designated person, it also facilitates delivery to the authorized person, such as when the authorized person is unavailable or unable to sign for delivery of the package.

This amendment is seen as risk neutral insofar as other MMAR provisions governing sending remain unchanged and a signature acknowledging receipt of the package at the destination will still be required. Since no new conditions of sending are imposed on designated or authorized persons, and no new services are demanded of courier companies or common carriers, the amendment is also viewed as cost neutral.

Physicians

Physicians, if they choose to support a patient's application, will benefit from the streamlining of the application and renewal processes. Completion of the required forms should be less time consuming. Also, the medical declarations physicians are required to complete in support of an application for authorization to possess are more reflective of the scientific information currently available and more sensitive to the unique role that physicians have been asked to play under the MMAR.

In addition, amendments to the physician and applicant declarations establish between the applicant and the physician a more appropriate sharing of responsibility for the decision to use marihuana as an alternative treatment.

The streamlined application process, including the reduced requirements for specialist involvement, could lead to an increase in the number of people seeking to use marihuana for medical purposes, which could in turn result in increased pressure on physicians to support patient applications. It must be noted, however, that while over 300 Canadian physicians have supported applications for authorization to possess marihuana for medical purposes, some physicians have chosen not to do so. Such a decision is clearly within the professional purview of the physician.

Canadian police agencies

Canadian police agencies will benefit from the inclusion of provisions in the Regulations that enable them to confirm whether any named individual or specified address is associated with an authority issued under the Regulations. With this information, unnecessary enforcement action can be avoided thereby

reducing safety risks for authorized and licensed persons, police and others in the community. Accessibility to this information may also reduce law enforcement costs for police agencies.

Health Canada

Streamlining of the application and renewal processes will reduce Health Canada's costs associated with reviewing and approving applications submitted under the MMAR. These cost savings, however, may be offset by the anticipated increase in the number of applications received by the Department as a result of the removal of some requirements, previously perceived as impediments to access.

Health Canada will incur additional costs to maintain a system for providing Canadian police with access to authorization and licence information 24 hours per day, 7 days per week. The indirect benefits of such a system, in terms of safeguarding the privacy of authorized and licensed persons, should offset the incremental system costs.

Health Canada plans to manage any additional costs within existing resource allocations. The Department believes that the benefits from these regulatory amendments, in terms of improving patient access to the medical marihuana program, and providing appropriate protections for public health and safety, outweigh the additional costs that may be incurred.

Canadian public

The public at large will benefit from increased safety resulting from the improved ability of police officers to be able to differentiate between legal and illegal marihuana-related activities and from decreased risk of exposure to unnecessary law enforcement action. These amendments may contribute to more efficient use of police resources and reduced law enforcement costs. A potential for decreased health care costs also exists due to reduced requirements for the involvement of specialists in the application process.

Consultation

Since the Regulations came into force in July 2001, Health Canada has received input concerning the MMAR via a variety of mechanisms, including a "1-800" number, a program e-mail address, and letters from patients, physicians and others. The Department commenced structured consultations with various stakeholder groups regarding plans to improve the MMAR early in 2003. A series of consultation sessions regarding the medical marihuana program was initiated in the fall of 2003 and sessions which focussed on the current Phase 2 amendments to the MMAR were conducted in January and February 2004. The groups engaged included

- the Stakeholder Advisory Committee on Medical Marihuana (SAC), a standing committee established in the fall of 2002 which includes representatives of patient, physician, nursing, pharmacist, and law enforcement groups;

- the Canadian Medical Association, the Federation of Medical Regulatory Authorities of Canada, and other representatives of Canadian physicians, in particular regarding the role of physicians in the MMAR process;

- the Canadian Pharmacists Association, the Canadian Society of Hospital Pharmacists, the National Association of Pharmacy Regulatory Authorities and other representatives of Canadian pharmacists and pharmacies, in particular regarding the feasibility of establishing a pharmacy-based system for the distribution of marihuana for medical purposes;

- representatives of Canadian police agencies, in particular regarding issues related to the communication of authorization and licence information to police; and

- organizations that represent authorized persons, licensed persons, and other Canadians likely to be affected by amendments to the MMAR.

On February 18, 2004, Health Canada held a multi-stakeholder consultation session in Ottawa involving approximately 45 interested parties external to the Department. The objective of this session was to bring the representatives of the key groups mentioned above together in a single forum to consider the proposed amendments to the MMAR, to discuss their different perspectives, and to provide the Department with their feedback.

By way of a notice posted on its Web site, Health Canada also invited Canadians to provide written input to the consultation process up until March 5, 2004.

Health Canada heard the following during the consultative process:

Patients expressed support for amendments to the MMAR that would streamline application and renewal processes and improve access to the medical marihuana program. They advocated more research into the safety, efficacy and quality of the product and alternative forms and routes of administration, and expressed willingness to assume from the physician a greater share of the responsibility for the decision to use marihuana for medical purposes. Patients generally acknowledged the need for Canadian police to have access to information that would allow them to identify marihuana-related activities associated with an authorization or licence issued under the MMAR. At the same time, they expressed concern about adequate safeguards to protect their privacy and prevent potential misuse of their personal information.

Physicians' opinions ranged from very supportive of providing compassionate access to marihuana for medical purposes to strongly opposed to the program. Those who were opposed expressed concerns that marihuana is not a medical product in a conventional sense, and that there is a relative lack of scientific information available to support informed recommendations about its use. Physicians generally expressed concerns that marihuana is most often ingested by smoking and encouraged the development of alternative forms and routes of administration. They encouraged more clinical research into the safety, efficacy and quality of marihuana, as well as the provision of educational material to physicians, patients and the public on the current body of scientific knowledge available regarding the use of marihuana for specific medical purposes.

Police were emphatic that timely confirmation of authorization and licence information is necessary to mitigate the risk of harm to authorized and licensed persons, police and others in the community as a consequence of unnecessary law enforcement action. They indicated their support for any proposal that would allow Canadian police to confirm authorization and licence information with Health Canada. On the other hand, police expressed concerns regarding continued personal cultivation of marihuana for medical purposes and the challenges this poses in the context of their efforts to eliminate illegal marihuana growth operations in Canada.

Pharmacists welcomed the prospect of a role for pharmacy in the medical marihuana program, particularly given the availability of a legal, standardized source and supply of the drug product. Pharmacists endorsed the proposal for a pilot project that would be based on a pharmaceutical care model and would potentially involve the dispensing of dried marihuana without a prescription. However, they expressed their continuing reservations with the smoked route of administration and encouraged further research into alternative forms and routes of administration, as well as into safety and efficacy of marihuana when used for specific medical purposes.

Compliance and enforcement

These regulatory amendments have little or no impact on the compliance and enforcement mechanisms currently employed by Health Canada in relation to the *Controlled Drugs and Substances Act* and the MMAR. Inspections of licensed production and storage sites are conducted on a random and complaints-driven basis.

The new provisions, which allow police officers to confirm authorization and licence information with Health Canada, will enhance the ability of Canadian police to investigate and take appropriate enforcement action in regards to any unauthorized marihuana-related activity including, for example, the production or storage of marihuana at locations other than those authorized, or trafficking in marihuana, which includes selling, giving, sending, delivering, or administering

marihuana to any person not named in the authorization or licence issued by Health Canada.

Contact

Ms. Cynthia Sunstrum, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch, Address Locator 3503D, Ottawa, Canada K1A 1B9, (613) 946-0125 (telephone), (613) 946-4224 (facsimile), OCS_Policy_and_Regulatory_Affairs@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* (see footnote a), proposes to make the annexed *Regulations Amending the 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 Cynthia Sunstrum, Drug Strategy and Controlled Substances Programme, Department of Health, Address Locator 3503D, Ottawa, Ontario K1A 1B9 (fax: (613) 946-4224; e-mail: cynthia_sunstrum@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, October 18, 2004

EILEEN BOYD
Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE MARIHUANA MEDICAL ACCESS REGULATIONS

AMENDMENTS

1. (1) The definitions "adverse drug reaction", "category 3 symptom" and "terminal illness" in subsection 1(1) of the *Marihuana Medical Access Regulations* (see footnote 1) **are repealed.**

(2) The definitions "category 1 symptom", "category 2 symptom" and "medical purpose" in subsection 1(1) of the Regulations are replaced by the following:

"category 1 symptom" means any symptom treated within the context of compassionate end-of-life care or a symptom set out in column 1 of the schedule that is associated with a medical condition set out in column 2 or with the medical treatment of that condition. (*symptôme de catégorie 1*)

"category 2 symptom" means a debilitating symptom that is associated with a medical condition or with the medical treatment of that condition and that is not a category 1 symptom. (*symptôme de catégorie 2*)

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

(3) Subsection 1(1) of the Regulations is amended by adding the following in alphabetical order:

"licensed dealer" has the same meaning as in section 2 of the *Narcotic Control Regulations*. (*distributeur autorisé*)

2. Paragraph 4(2)(*b*) of the Regulations is replaced by the following:

(*b*) a medical declaration made by the medical practitioner treating the applicant; and

3. Paragraphs 5(1)(*e*) to (*g*) of the Regulations are replaced by the following:

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

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

(ii) obtained under section 70.2 from a licensed dealer producing marihuana under contract with Her Majesty in right of Canada or obtained from a medical practitioner under section 70.4;

(*f*) that the applicant 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;

(*g*) that the applicant has discussed the potential benefits and risks of using marihuana with the medical practitioner providing the medical declaration under paragraph 4(2)(*b*);

(*h*) that the applicant

(i) is aware that the benefits and risks associated with the use of marihuana are not fully understood and that the use of marihuana may involve risks that have not yet been identified, and

(ii) accepts the risks associated with using marihuana;

(*i*) if the daily amount stated under paragraph 6(1)(*c*) is more than five grams, that the applicant

(i) has discussed the potential risks associated with an elevated daily consumption of dried marihuana with the medical practitioner providing the medical declaration, including risks with respect to the effect on the applicant's cardio-vascular and pulmonary systems and psychomotor performance, risks associated with the long-term use of marihuana as well as potential drug dependency, and

(ii) accepts those risks; and

(*j*) that marihuana will be used only for the treatment of the symptom stated for the applicant under paragraph 6(1)(*b*).

4. Section 6 of the Regulations is replaced by the following:

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

(*a*) the medical practitioner's name, business address and telephone number, facsimile transmission number and e-mail address if applicable, the province in which the practitioner is authorized to practise medicine and the number assigned by the province to that authorization;

(*b*) the name of the applicant, 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 or 2 symptom;

(*c*) for the purpose of determining, under subsection 11(3), the maximum quantity of dried marihuana to be authorized, the daily amount of dried marihuana, in grams, and the form and route of administration that the applicant intends to use;

(*d*) the anticipated period of usage, if less than 12 months;

(*e*) that conventional treatments for the symptom have been tried or considered and have been found to be ineffective or medically inappropriate for the treatment of the applicant; and

(*f*) that 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.

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

(*a*) if the medical practitioner making the medical declaration is a specialist, the practitioner's area of specialization and that the area of specialization is relevant to the treatment of the applicant's medical condition; and

(*b*) if the medical practitioner making the medical declaration is not a specialist,

(i) that the applicant's case has been assessed by a specialist,

(ii) the name of the specialist,

(iii) the specialist's area of specialization and that the area of specialization is relevant to the treatment of the applicant's medical condition,

(iv) the date of the specialist's assessment of the applicant's case,

(v) that the specialist concurs that conventional treatments for the symptom are ineffective or medically inappropriate for the treatment of the applicant, and

(vi) that the specialist is aware that marihuana is being considered as an alternative treatment for the applicant.

5. Section 8 of the Regulations is replaced by the following:

8. A medical declaration under paragraph 4(2)(*b*) must be dated and signed by the medical practitioner making it and must attest that the information contained in the declaration is correct and complete.

6. Section 9 of the Regulations and the heading before it are repealed.

7. Paragraph 10(*d*) of the Regulations is replaced by the following:

(*d*) be certified, on the reverse side, by the medical practitioner making the medical declaration under paragraph 4(2)(*b*) to be an accurate representation of the applicant.

8. Section 11 of the Regulations is replaced by the following:

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 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 of the medical practitioner who made the medical declaration under paragraph 4(2)(*b*);

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

(*f*) the date of issue; and

(*g*) the date of expiry.

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

$$A \times 30$$

where A is the daily amount of dried marihuana, in grams, stated under paragraph 6(1)(*c*) or subparagraph 19(2)(*d*)(i), whichever applies.

9. Subsection 12(1) of the Regulations is amended by adding the word "or" at the end of paragraph (*a*), by striking out the word "or" at the end of paragraph (*b*) and by repealing paragraph (*c*).

10. Subsection 14(2) of the Regulations is replaced by the following:

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

11. Sections 15 and 16 of the Regulations are repealed.

12. Section 18 of the Regulations is replaced by the following:

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

13. Sections 19 to 22 of the Regulations are replaced by the following:

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 holder's name;

(*b*) the holder's address of ordinary residence or mailing address; or

(*c*) the daily amount of dried marihuana if the new amount requires an increase in the maximum quantity of dried marihuana, in grams, that the holder may possess at any time.

(2) The application must include

(*a*) the authorization number and, if applicable, the licence number of the licence to produce that has been issued on the basis of the authorization;

(*b*) the requested amendment;

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

(*d*) in the case of a change under paragraph (1)(*c*),

(i) a statement containing the information required under paragraph 6(1)(*c*), signed and dated by the medical practitioner who made the medical declaration under paragraph 4(2)(*b*), and

(ii) if the new daily amount is more than five grams, the statement required under paragraph 5(1)(*i*), signed and dated by the applicant.

20. (1) Subject to subsection (2), if an application complies with section 19, the Minister shall amend the authorization to possess.

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

21. (1) If an authorization to possess is amended 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.

(2) If an authorization to possess is amended with respect to the daily amount 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 of the licence may produce and the maximum quantity of dried marihuana that the holder of the licence may keep.

14. Section 23 of the Regulations is replaced by the following:

23. While in the presence of the holder of an authorization to possess and providing assistance in the administration 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 an amount equal to the maximum quantity of dried marihuana the holder is authorized to possess as set out in the authorization to possess, divided by 30.

15. The heading before section 26 of the Regulations is replaced by the following:

Application for Licence

16. The heading before section 27 of the Regulations is repealed.

17. (1) Paragraph 30(1)(*a*) of the Regulations is replaced by the following:

(*a*) "A" is the daily amount of dried marihuana, in grams, stated under paragraph 6(1)(*c*) or subparagraph 19(2)(*d*)(i), whichever applies;

(2) Paragraph 30(1)(*c*) of the Regulations is replaced by the following:

(*c*) "D" is the maximum number of marihuana plants referred to in subsection 21(2) and paragraphs 29(2)(*f*) and 40(2)(*g*).

18. (1) The portion of subsection 31(1) of the English version of the Regulations before paragraph (*a*) is replaced by the following:

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

(2) Paragraph 31(1)(*b*) of the Regulations is replaced by the following:

(*b*) "E" is the maximum quantity of dried marihuana mentioned in subsection 21(2) and in paragraphs 29(2)(*h*) and 40(2)(*i*).

19. Subsection 34(1.1) of the Regulations is replaced by the following

(1.1) A holder of a designated-person production licence sending dried marihuana under paragraph (1)(*d*) shall

(*a*) securely pack the marihuana in a package that

(i) will not open or permit the escape of its contents during handling and transportation,

(ii) is sealed so that the package cannot be opened without the seal being broken,

(iii) prevents the escape of odour associated with the marihuana, and

(iv) prevents the contents from being identified without the package being opened; and

(*b*) use a method of sending that involves

(i) a means of tracking the package during transit,

(ii) obtaining a signed acknowledgment of receipt, and

(iii) safekeeping of the package during transit.

20. The heading before section 36 of the Regulations is replaced by the following:

Application for Licence

21. The heading before section 37 of the Regulations is repealed.

22. Section 51 of the Regulations and the heading before it are repealed.

23. The headings before section 58 of the Regulations are replaced by the following:

PART 3

GENERAL OBLIGATIONS

Documents

24. Subsection 58(1) of the English version of the Regulations is replaced by the following:

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

25. The heading before section 59 and sections 59 and 60 of the Regulations are replaced by the following:

59. No one may add to, delete or obliterate from, or alter in any other way, an authorization to possess, a licence to produce or any other document provided to the holder of an authorization to possess or a licence to produce as proof of their authorization or licence.

60. (1) If an authorization to possess, licence to produce or any other document provided to the holder of an authorization to possess or a licence to produce as proof of their authorization or licence is amended, the holder of the authorization or licence shall, within 30 days after receiving the amended document, return the replaced document to the Minister.

(2) If an authorization to possess or licence to produce is revoked, the holder of the authorization or licence shall, within 30 days after the revocation, return to the Minister the revoked document and any other document provided to the holder of the authorization or the licence as proof of their authorization or licence.

26. Paragraph 62(2)(*b*) of the Regulations is replaced by the following:

(*b*) the medical practitioner who made the medical declaration under paragraph 4(2)(*b*) for the holder of the authorization advises the Minister in writing that the continued use of marihuana by the holder is contraindicated.

27. The heading before section 68 of the English version of the Regulations is replaced by the following:

Complaints and Communication of Information

28. Subsection 68(3) of the Regulations is replaced by the following:

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

29. The Regulations are amended by adding the following after section 68:

68.1 In response to a request from a Canadian police force or a member of a Canadian police force engaged in an investigation under the Act or these Regulations, the Minister is authorized, for the purpose of that investigation and

the proper administration or enforcement of the Act or these Regulations, to communicate

(*a*) in respect of a named individual, whether the individual is the holder of an authorization to possess or a licence to produce;

(*b*) in respect of a specified address, whether the address is

(i) the place where the holder of an authorization to possess ordinarily resides and, if so, the name of the holder of the authorization and the applicable authorization number,

(ii) the site where the production of marihuana is authorized under a licence to produce and, if so, the name of the holder of the licence and the applicable licence number, or

(iii) the site where dried marihuana may be kept under a licence to produce and, if so, the name of the holder of the licence and the applicable licence number;

(*c*) in respect of an authorization to possess,

(i) the name, date of birth and gender of the holder of the authorization,

(ii) the full address of the place where the holder ordinarily resides,

(iii) the authorization number,

(iv) the maximum quantity of dried marihuana that the holder is authorized to possess,

(v) the dates of issue and expiry, and

(vi) if the authorization has expired, whether an application to renew the authorization has been made prior to the date of expiry and the status of the application; and

(*d*) in respect of a licence to produce,

(i) the name, date of birth and gender of the holder of the licence,

(ii) the full address of the place where the holder ordinarily resides,

(iii) the licence number,

(iv) the full address of the site where the production of marihuana is authorized,

(v) the authorized production area,

(vi) the maximum number of marihuana plants that may be under production at the production site at any time,

(vii) the full address of the site where dried marihuana may be kept,

(viii) the maximum quantity of dried marihuana that may be kept at the site referred to in subparagraph (vii) at any time,

(ix) the dates of issue and expiry, and

(x) if the licence has expired, whether an application has been made to renew the licence prior to the date of expiry and the status of the application.

30. Part 4 of the Regulations is replaced by the following:

PART 4

SUPPLY OF MARIHUANA SEED
AND DRIED MARIHUANA

Marihuana Seed

70. The Minister is authorized to import and possess viable cannabis seed for the purpose of selling, providing, transporting, sending or delivering the seed to

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

(*b*) a licensed dealer.

70.1 A licensed dealer producing viable cannabis seed under contract with Her Majesty in right of Canada may provide or send that seed to the holder of a licence to produce.

Dried Marihuana

70.2 A licensed dealer producing dried marihuana under contract with Her Majesty in right of Canada may provide or send that marihuana to the holder of an authorization to possess.

70.3 A pharmacist, as defined in section 2 of the *Narcotic Control Regulations*, may provide dried marihuana produced by a licensed dealer under contract with Her Majesty in right of Canada to the holder of an authorization to possess.

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

70.5 The Minister may sell or provide dried marihuana produced in accordance with section 70.2 to the holder of an authorization to possess.

31. The schedule to the Regulations is replaced by the following:

SCHEDULE
(Section 1)

CATEGORY 1 SYMPTOMS

Item	Column 1 Symptom	Column 2 Associated Medical Conditions
1.	Severe nausea	Cancer, AIDS/HIV infection
2.	Cachexia, anorexia, weight loss	Cancer, AIDS/HIV infection
3.	Persistent muscle spasms	Multiple sclerosis, spinal cord injury or disease
4.	Seizures	Epilepsy
5.	Severe pain	Cancer, AIDS/HIV infection, multiple sclerosis, spinal cord injury or disease, severe form of arthritis

COMING INTO FORCE

32. These Regulations come into force on the day on which they are registered.

[43-1-o]

Footnote a

S.C. 1996, c. 19

Footnote 1

SOR/2001-227

NOTICE:
The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.