



Medical Marijuana

Background

In 2001, Health Canada enacted a preliminary set of "marijuana medical access regulations" (MMAR). These were in response to an Ontario Court of Appeal finding that banning marijuana for medicinal purposes violated the Charter of Rights and Freedoms.¹ The MMARs, as enacted, were designed to establish a framework to allow the use of marijuana for the relief of pain, nausea and other symptoms by people suffering from serious illness where conventional treatments had failed.

In developing the preliminary MMARs, Health Canada asked for feedback from key stakeholders, including the Canadian Medical Association (CMA). While recognizing the needs of those suffering from terminal illness or chronic disease, CMA raised strong objections to the proposed regulations. In particular, there were concerns about the lack of evidence on the risks and benefits associated with the use of marijuana. This made it difficult for physicians to properly advise their patients and properly manage doses or potential side effects. Additionally, there were concerns about medico-legal liability, corroborated by the Canadian Medical Protective Association (CMPA).

While acknowledging some of the concerns of the CMA, the regulations were passed in July 2001, without sufficient change to gain CMA's support. There remained fundamental concerns about

quality, safety and efficacy of medical marijuana. The medico-legal liability concerns remained, prompting the CMPA to issue an information sheet for physicians and to encourage those uncomfortable with the regulations to refrain from prescribing marijuana to patients.

In January 2003, the Ontario Superior Court ruled that the MMARs failed to provide a legal supply of marijuana for those persons entitled to possess it for medicinal purposes. Therefore, the regulations were deemed constitutionally invalid with no force or effect. The decision was suspended for six months in order to give Health Canada time to remedy the situation.²

Subsequently, in 2003, Health Canada presented an "Interim Policy", which included provisions for the production and distribution of medical marijuana to authorized patients. CMA vigorously opposed this policy, which exacerbated rather than addressed the fundamental concerns of the profession by making physicians part of the supply chain.

The CMA raised strong concerns about the implications of both the original regulations and the interim policy for both patients and physicians, stating that physicians should not be put in the untenable position of gatekeepers for a proposed medical intervention that had not undergone established regulatory review processes as required for all other prescription medicines.

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At General Council in 2003, delegates passed the following motions:

That Canadian Medical Association strongly oppose the use of marijuana for medical reasons in the absence of supporting scientific evidence.

That Canadian Medical Association recommends that physicians not participate in the dispensing of medical marijuana under the existing Medical Marijuana Access Regulations.

New regulations (introduced in June 2005) reduced the onus on physicians to declare the need for, and dose of marijuana, focusing instead on an attestation of diagnosis and failure of conventional therapies. These amendments were seen as an improvement to the previous MMARs as they reduced the obligation of a physician to declare that the proposed therapy was efficacious. While continuing to oppose the medical use of marijuana and recommending that physicians not participate in the program because of the failure of governments and manufacturers to provide adequate information regarding safety, CMA accepts that physicians who feel qualified to recommend medical marijuana to their patients do so in accordance with the regulations.

Current Situation

The MMARs have undergone a number of further revisions since 2005. For the most part, these revisions have been in response to decisions from various courts across the country. Courts have consistently sided with patients' rights to relieve symptoms of terminal disease or certain chronic conditions, despite the limited data on the effectiveness of marijuana. Courts have not addressed the ethical position in which physicians are placed as a result of becoming the gate keeper for access to a medication without full knowledge of its effectiveness, proper dosage, or short and long-term side effects. As of June 2009, there were 4,029 people licensed to possess dried marijuana for medical purposes.³ In 2009, General Council passed a resolution urging the CMA to:

- a) *update its policy on medical marijuana; and*
- b) *ask the federal government to update the medical marijuana access program and regulations following appropriate consultations with stakeholders and scientific advisory committees, and reinstate support for research into the safety and efficacy of medical marijuana and cannabinoids.*

Following the passage of this resolution, the Office for Public Health (OPH) began a review of the published literature on medical marijuana. Evidence exists about pharmaceutically prepared, orally administered marijuana alternatives. Commonly referred to as cannabinoids, these drugs utilize the active ingredient in marijuana, delta-9-tetra-hydrocannabinol (THC), and are dispensed in pill or vaporized format.⁴ Pharmaceutical cannabinoids have undergone clinical trials to demonstrate safety and effectiveness, and have been approved for use through the Food and Drug Act of Canada. Of note is that in this format, the toxic by-products of smoked marijuana are avoided.⁵

In summary, there remains scant evidence regarding the effectiveness of the herbal form of marijuana (e.g. smoked) as accessed through Health Canada's MMAR program. The generalizability of the conclusions from published studies are limited by methodology (double blind placebo controlled trials are not possible; previous users of marijuana are often excluded) and very small sample sizes. While it may be the case that medical marijuana is efficacious, scientific evidence comparable to other prescription pharmaceuticals is still lacking. Additionally, there is insufficient information about long-term effects and pharmacodynamics such as interactions with other medications and dose-response curves.

The OPH met with representatives from the Controlled Substances and Tobacco Directorate of Health Canada, which oversees the MMARs. Concerns regarding the limited data on effectiveness, the difficulties with assessing proper dosage, long term health effects of inhaled marijuana and pharmacodynamics were shared.

As previously noted, the Federal government is constrained by the decisions of Canadian courts. They are currently reviewing the MMARs and plan to consult further with CMA regarding research, physician responsibilities and education programs for Canada's physicians. The OPH met with Margaret Bloodworth, a contractor hired by Health Canada to do a full assessment of the program.

CMA Position:

The CMA has always recognized and acknowledged the unique requirements of those individuals suffering from a terminal illness or chronic disease for which conventional therapies have not been effective and for whom marijuana for medicinal purposes may provide relief. However, there are a number of problems with the current Medical Marijuana access program. In order to find a solution to these outstanding problems, CMA makes the following recommendations.

1. The advancement of scientific knowledge about medical marijuana must be encouraged. Given that there are currently over 4,000 patients receiving medical marijuana from Health Canada, CMA encourages the Government to properly study the safety, efficacy, most appropriate amount to be used, and the most effective delivery mechanism for treatment of specific conditions. The same safety and evidence standards should apply to medical marijuana as to pharmaceutical products under the FDA.
2. With the increasing number of patients being authorized to possess medical marijuana, it is imperative that physicians know and understand the regulations and the use of medical marijuana in their practice settings. As such, CMA calls on the Government to work with the CMA, The College of Family Physicians of Canada, the Royal College of Physicians and Surgeons, and other relevant stakeholders, to develop compulsory education and licensing programs for

physicians who authorize the use of marijuana for their patients.

3. Finally, until the problems with the MMARs are rectified, CMA lacks the basis upon which to revise its current policy. Physicians who wish to authorize the use of marijuana for patients in their practices should consult relevant CMPA policy and guidelines in order to ensure appropriate medico-legal protection.

References

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 - ² *Hitzig v. Canada*, 2003 CanLII 3451 (ON S.C.). Available at: <http://www.canlii.org/en/on/onsc/doc/2003/2003canlii3451/2003canlii3451.html>
 - ³ Health Canada (2009) *Marihuana for Medical Purposes Statistics June 5, 2009*. Available at: (http://www.hc-sc.gc.ca/dhp-mps/marihuana/stat/_2009/june-juin-eng.php)
 - ⁴ Ware, Mark A.; Kahan, Meldon, and Anita Srivastava (2006) "Is there a role for marijuana in medical practice?" *Canadian Family Physician* Vol 52: December pp. 1531-1533.
 - ⁵ Engels, Frederike K. et.al. (2007) "Medicinal cannabis in oncology." *European Journal of Cancer*. 43(2007) pp. 2638-2644,