

CMA Response: Health Canada's Medical Marijuana Regulatory Proposal

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A healthy population and a vibrant medical profession
Une population en santé et une profession médicale
dynamique

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.

On behalf of its more than 77,000 members and the Canadian public, CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 51 national medical organizations.



The Canadian Medical Association welcomes the opportunity to comment on proposed changes to Health Canada's *Marihuana for Medical Purposes Regulations*, published in the *Canada Gazette, Part I* on December 15, 2012.

CMA provided comments on the proposed changes when Health Canada first announced them in June 2011. Our position on these changes, and indeed on the entire *Medical Marihuana Access Program* (MMAP), has been consistent since the program was initiated. We remain deeply concerned that, though the program has made a physician's authorization the key to a patient's access to medical marijuana, physicians and other health professionals have little to no evidence-based information about its use as medical therapy. As our President, Dr. Anna Reid, noted in December, the regulatory proposals are "equivalent to asking doctors to prescribe while blindfolded."

Health Canada gives two reasons for its regulatory proposal: first, to address concerns about the safety of home grow-ops; and secondly, to reduce the cost of administering a program that has proven more popular than anticipated. Neither of these reasons is related to improving patient care or advancing our clinical knowledge of marijuana as a medical treatment.

CMA understands that many Canadians suffer constant pain from chronic or terminal illnesses and are searching for anything that will provide relief. We know that some patients find that use of marijuana relieves their symptoms and that some health professionals also believe it has therapeutic value. However, we are concerned that these claims remain inadequately supported by scientific research. Controlled studies of medical marijuana have been published recently and some have shown benefits. However, these studies are few in number, of short duration and with small samples, and knowledgeable clinicians say that more research is required. In addition, some say that marijuana has become more potent since it became a popular recreational drug in the 1960s, though others disagree,¹ and growers say they can develop strains tailored to the needs of individual medical users.² Though these claims are part of the popular understanding of medical marijuana, there is no scientifically valid evidence that supports them.

What Physicians Have Told Us

In May 2012, CMA surveyed members of its "e-panel" of physicians to obtain more information about their attitudes and needs regarding medical marijuana. The survey received just over 600 responses out of more than 2,200, for a 27 per cent response rate. Among the findings:

- About 70 per cent of respondents had been asked by patients to approve medical marijuana, though only four per cent said they were asked to do so "often." Of those

¹ Bonsor K: "How marijuana works". Accessed at <http://science.howstuffworks.com/marijuana5.htm>

² <http://medicalmarijuana.ca/learning-center/marijuana-strains>

who were asked, one-third reported that they “never” supported such requests, while 18 per cent “usually” did so.

- 64 per cent of respondents were concerned that patients who request medical marijuana may actually be using it for recreational purposes;
- A large majority of respondents said they would find more information on the appropriate use of marijuana for medicinal purposes, and on its therapeutic benefits and risks, useful or very useful.
- About two-thirds agreed or strongly agreed that they would feel more comfortable if:
 - Physicians wishing to use medical marijuana in their practices were required to undergo special training and licensing; and,
 - Health Canada offered them protection from liability.
- In open-ended questions, some respondents expressed favourable views on marijuana’s medical benefits. However, a larger number expressed concern over its harmful effects, such as: psychotic symptoms, especially in younger people; potential for addiction and dependency; and the risks to lung health from smoking it or any other substance.

Marijuana is Not Like Other Therapeutic Products

Theoretically, marijuana, when used for medicinal purposes, is regulated under the *Food and Drugs Act*. However, because of its unique legal position, Health Canada has exempted it from the applications of the *Act* and its regulations, and it has not undergone the scrutiny of benefits and risks required of other therapeutic products approved for use in Canada, be they prescription-only or over-the-counter.

According to the *Food and Drugs Act (FDA)*, all drugs requiring a health professional’s authorization must be approved for use by Health Canada, based on evidence of effectiveness obtained from controlled clinical trials, which remain the best currently available means of validating knowledge. In addition, Health Canada has a system of post-market surveillance to keep track of problems that arise with prescription drugs in real-world use. Though the CMA has been critical of some aspects of this system,³ we acknowledge that it has added to our body of knowledge on drug safety risks. If marijuana were not an illegal product, it might have been assessed through some form of pre-approval and post-approval surveillance. By exempting marijuana from the *FDA*’s pre-approval and post-approval requirements, Health Canada has lost an opportunity to improve our knowledge of the drug’s therapeutic uses.

³ CMA Submission to the House of Commons Standing Committee on Health: Post-Market Surveillance of Prescription Drugs (February 28, 2008). Accessed at http://www.cma.ca/multimedia/CMA/Content_Images/Inside_cma/Submissions/2008/brief-drug-en-08.pdf

The Views of Canadians

A recent online survey conducted by Ipsos-Reid on behalf of the CMA provides insight into the views of Canadians on Health Canada's regulatory proposal.⁴ The survey found:

- 92 per cent of Canadians think it is very or somewhat important that Health Canada not remove itself from its oversight role until guidelines are put in place for physicians;
- 90 per cent believe that research on the effectiveness, safety and risks of medical marijuana is needed before Health Canada removes itself from the authorization process;
- 85 per cent of Canadians believe medical marijuana should be subject to the same rigorous testing and approval standards as other medicines;
- 79 per cent agree that Health Canada has a responsibility to maintain its role in the authorization process.;

The Role of the Physician

The CMA cannot with certainty predict the consequences of these regulatory changes for the practising physician (and, if the regulations are approved, for the nurse practitioner as well). However, we have several causes for concern:

- *The gatekeeper role of health professionals:* The most significant change, from our point of view, is that Health Canada is removing itself from the approval process, making it a transaction between the patient, the practitioner and the licensed producer. In addition, Section 125 of the regulatory proposal would reduce the content of the authorization form, from its current two-page format to a brief document requiring little more information than is required for a standard medical prescription.

We are concerned that these changes will put an even greater onus on physicians than do the current regulations. The CMA agrees with the Federation of Medical Regulatory Authorities that the lack of evidence to support the use of marijuana for medicinal purposes signifies that it is not a medical intervention. In our opinion, putting physicians in the role of gatekeeper for access to marijuana is inappropriate and may be an abdication of responsibility on Health Canada's part.⁵ Such a move could increase physicians' liability risk and put them at odds with their medical regulatory authorities, which have no choice but to continue to advise physicians to exercise extreme caution.

The CMA believes, as does the Canadian Medical Protective Association, that a drug's approval under the *Food and Drugs Act* does not impose a legal obligation on physicians or nurse practitioners to authorize its use if, in their judgment, it is clinically inappropriate.

⁴ Online survey of 1,000 Canadians the week of Feb. 24, 2013 conducted by Ipsos-Reid. Summary report of the poll can be accessed at www.cma.ca/advocacy/cma-media-centre.

⁵ Letter to Health Canada from Yves Robert, MD, President of the Federation of Medical Regulatory Authorities of Canada, November 4, 2011.

The Ontario Court of Appeal reached a similar decision recently in the case of *R. v. Mernagh*.

- *Protection of Physician Privacy.* Under the proposed regulations, health information and physician data – such as the patient’s name and date of birth, or the provider’s licence number – will be collected by licensed producers who may not be subject to the same regulatory and privacy constraints as the health care sector. The draft regulations also indicate that the licensed producer is expected to confirm that the data on the “medical document” is correct and complete – in other words, health providers who authorize medical marijuana use will receive correspondence from the producer. We are very concerned about the risks this would pose to the privacy of patient and health care provider information. We believe Health Canada should conduct a privacy impact assessment of its proposed regulations or, if it has done so, to share the results.
- *Physicians as Dispensers.* Section 124 of the proposed regulations would allow authorized health care practitioners to “sell, provide or administer dried marijuana.” This is contrary to Article 46 of the CMA Guidelines for Physicians in Interactions with Industry, which states that “Physicians should not dispense pharmaceuticals or other products unless they can demonstrate that these cannot be provided by an appropriate other party.”⁶
- *Other possible consequences.* We are also concerned about other potential consequences of the regulatory changes. Will more people go to health professionals requesting an authorization, on the assumption that the new regulations will make it easier to get? Will entrepreneurs seize the opportunity to establish “dispensaries” whose intended clientele are not those in legitimate medical need, as recent news stories have suggested?⁷ Will medical marijuana advocates put increased pressure on physicians to authorize its use?

Meeting the Information Needs of Physicians

In one respect, Health Canada has listened to physicians’ concerns regarding the lack of evidence about medical marijuana, and acknowledged the need to remedy this problem. Though it is not addressed in the draft regulations, Health Canada has established an Expert Advisory Committee (EAC) to help provide comprehensive information to health professionals. The CMA has attended meetings of this committee in an observer capacity, suggested the names of practising physicians to serve as members, and made a presentation to the committee at its meeting in November 2012.

⁶ CMA. 2004. *Guidelines for Physicians in Interactions with Industry*. Guideline can be accessed online: <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf>

⁷ Lee J. “Ross Rebagliati to Open medical marijuana franchise.” *Vancouver Sun*. January 23, 2013. Accessed at <http://www.vancouversun.com/health/Ross+Rebagliati+open+medical+marijuana+franchise/7860946/story.html>

If the EAC follows the CMA's suggestions, it will consider actively supporting the following activities:

- Funding of scientific research on the clinical risks and benefits of marijuana;
- Knowledge translation activities to convert this research into accessible, user-friendly tools for education and practice;
- Development of best practice guidelines in the therapeutic use of marijuana. Though this guideline would of necessity be based on "C" level evidence, it would be an improvement on what now exists; and
- Support for a compulsory training and licensing program for physicians wanting to authorize marijuana for medicinal purposes.

The CMA believes that the EAC should be given the mandate and resources to undertake these activities.

Conclusion

Health Canada's stated mission is to help the people of Canada maintain and improve their health. The CMA believes that if Health Canada wants its Medical Marijuana Access Program to serve this mission, it should not withdraw from administering the program, leaving it to health professionals working within a large knowledge gap. Rather, it should support solid research into the use of marijuana as medication and make a commitment to share this knowledge with the health professional community and to support best clinical practices.