



Federation of  
Medical Regulatory  
Authorities of Canada

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**BY EMAIL**

Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Ottawa ON K1A 0K9

**Subject: Consultation on the Proposed Marijuana for Medical Purposes Regulations  
as per the Canada Gazette, Vol. 146, No. 50 – 15 December, 2012**

Dear Sir / Madam,

On behalf of the Federation of Medical Regulatory Authorities of Canada (FMRAC) and its Members, it is my privilege to comment on Health Canada's *Proposed Marijuana for Medical Purposes Regulations* and to reaffirm FMRAC's position on this issue.

**I would like to begin by requesting that, for purposes of transparency and completeness, this submission be posted in its entirety on the section of the Health Canada website dealing with marijuana for medical purposes.**

As we have stated several times, most recently in our submission dated 4 November 2011, FMRAC's formal position has not changed since the implementation of this program:

*The Federation of Medical Regulatory Authorities of Canada strongly believes that the practice of medicine should be evidence-based, and that physicians should not be asked to prescribe or dispense substances or treatments for which there is little or no evidence of clinical efficacy or safety. (2004)*

For those stated reasons, we strongly oppose the proposed *Marijuana for Medical Purposes Regulations*.

### ***Role of Physicians***

The program, as it was originally designed, restricted the role of physicians to providing a written confirmation of the patient's medical condition, attesting to the fact that it was among the conditions that allowed access to marihuana for medical purposes.

FMRAC believes that, at most, this restricted role should remain as originally described. This would avoid the clinical and regulatory challenges physicians would face in prescribing a substance like marihuana that is not an approved drug, narcotic or otherwise. For it to be a "prescribable" drug, it would have had to undergo the requisite scientific and clinical assessments, so that a body of evidence exists as to its efficacy and safety. As things currently stand, no such evidence exists, which is confirmed by Health Canada's own decision not to approve dried marihuana as a therapeutic product. Furthermore, unlike other drugs, it is not possible to standardize the dosage, therapeutic blood concentration, health benefit or even route of administration. In addition, there are no safety data. FMRAC continues in its firm view that, until such evidence is available or until Health Canada decides to approve marihuana as a therapeutic product like any other drug used in this country, it will not be possible for a physician to "prescribe" marihuana in the same manner as other prescription drugs.

FMRAC does not support the proposed changes and certainly does not support changes to the regulations that would allow physicians to sell, dispense or administer dried marihuana. Several jurisdictions strictly control the role of physicians in selling drugs that are on the schedule. This restriction will certainly extend to a product like marihuana that is not an approved drug.

Being both a prescriber and a dispenser of drugs creates a natural conflict of interest, which is why physicians will rarely assume or accept both roles. The prescriber (or in the case of these regulations the 'authorizer') has a fiduciary duty to the patient to first make a diagnosis, consider what treatment options are available, and then offer a treatment which must be in the patient's best interest. When one is also a dispenser, the safeguards of a separate, unconflicted professional are removed, and the interests of the patient may be lost.

In addition, the idea that physicians could sell, dispense or administer marihuana would have the effect of putting a target on the back of such physicians, assuming that a target has not already been attached to the physician as prescriber. We believe it is irresponsible for Health Canada to download the risks, legal and otherwise, to physicians as gatekeepers to marihuana.

### ***The need for evidence***

We hope that the Expert Advisory Committee established by Health Canada will move quickly to ensure the appropriate research is carried out as this is the only way that physicians will eventually have accurate information on which to make evidence-based decisions about prescribing dried marihuana which comply with clinical and regulatory requirements. This is long overdue.

### *Decriminalization of marihuana*

The recreational supply and distribution of marihuana are having profound adverse impacts on our communities. A more tightly regulated supply and distribution of marihuana for those who wish to use it for medical reasons may help mitigate some of these impacts. That being said, some jurisdictions in the United States have recently decriminalized the use of marihuana, mostly because they realized that regulating the use of this product for medical purposes was not feasible.

In addition to research to secure the appropriate evidence, FMRAC also stands firmly behind the need for the appropriate legal framework as the best means of ensuring safe access to all currently unrecognized treatments, including marihuana.

Perhaps it is time to take this issue out of the hands of the medical and other health care professionals and put it back squarely where it belongs: with those responsible for amending the Criminal Code of Canada.

### *In summary*

#### **We have grave concerns about the proposed regulations and strongly oppose them in their current form:**

- The lack of evidence to support the use of marihuana for medical purposes, indicated by Health Canada's own decision not to approve dried marihuana as a therapeutic product, continues to be a significant and grave concern:
  - o this lack of evidence signifies that this is not a medical intervention;
  - o this lack of evidence makes it inappropriate for Health Canada to put physicians in the role of gatekeeper for access to marihuana for medical purposes, and would seem to indicate an abdication of responsibility on the part of Health Canada, as physicians do not have the professional authority to do this.
- There are other options that should take precedence over the proposed changes to the regulations, i.e.:
  - a) retain the status quo, i.e., the physician can only confirm a medical diagnosis;
  - b) proceed with the proposed regulations **only on the condition** that dried marihuana has been approved by Health Canada as a therapeutic product, i.e., requiring research (to determine dosage, side effects, etc.), there is a legitimate producer and there is an approved prescribed drug distribution process; and
  - c) request that the Federal Government decriminalize the use of marihuana (it should be noted that this suggestion does not have the unanimous support of all FMRAC's Members).
- The Expert Advisory Committee should be well resourced to direct research leading to supporting (or refuting) evidence for the use of marihuana for medical purposes.
- Finally, physicians must not be requested to sell, dispense and administer marihuana.

We trust these comments are useful and we look forward to the results of this broad consultative process.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'H. Oetter', with a stylized flourish at the end.

Heidi Oetter MD  
President

Copy: The Hon. Leona Aglukkaq, Minister of Health  
Registrars, provincial and territorial medical regulatory authorities  
Dr. Anna Reid and Mr. Paul-Émile Cloutier, Canadian Medical Association  
Ms. Anne L. Coghlan, Canadian Council of Registered Nurse Regulators  
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