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THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

Bureau of Medical Marihuana Regulatory Reform
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To Whom It May Concern:

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

The College of Physicians and Surgeons of Ontario (CPSO) appreciates the opportunity to comment on the proposed changes to Health Canada's Marihuana Medical Access Program, as set out in the new draft *Marihuana for Medical Purposes Regulations*.

The CPSO has carefully reviewed the consultation materials and notes that the proposed changes to the program are substantively the same as the changes proposed by Health Canada in June 2011. As such, the comments we are providing at this time are consistent with, and expand on, the points articulated in our July 2011 submission.

The CPSO has significant concerns with Health Canada's proposed changes to Marihuana Medical Access Program. In summary, these are as follows: concerns regarding Health Canada's characterization of dried marijuana as a drug which must be prescribed, and the extent to which the provisions of the draft regulations will accord with expectations for safe prescribing and professional conduct; and concerns regarding potential negative implications the draft regulations will have for patients and physicians.

Consequently, the CPSO respectfully requests that Health Canada reconsider the approach articulated in the draft regulations. We also request that you share the CPSO's response letter in its entirety with the Honourable Leona Aglukkaq, Minister of Health.

1. Dried Marijuana: Expectations for Safe Prescribing and Professional Conduct

The CPSO notes that in the draft regulations, Health Canada is proposing to treat dried marijuana like a drug that is prescribed by health care practitioners. This is particularly evident as the information required on a medical document is much more prescriptive than what is currently required, and as certain provisions of the *Narcotic Control Regulations* will now apply to dried marijuana. This is a significant change because under the current program, physicians are simply completing a medical declaration, and this is not considered "prescribing".

The CPSO questions Health Canada's rationale for treating dried marijuana as a drug which must be prescribed, given the following:

- At present, dried marijuana is not an approved therapeutic product, as it has not met Health Canada's regulatory requirements for safety, efficacy and quality.
- The proposed regulations require that physicians identify the dosage of dried marijuana that will be prescribed to patients. Unlike other drugs, physicians will not have access to the information necessary to determine the appropriate dosage. Information regarding the delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) content of products is not standardized, and would not be available to physicians.¹
- There does not appear to be a clinical need for physicians to prescribe dried marijuana, as they can already prescribe products that contain cannabis that have been approved by Health Canada, such as Sativex and Cesamet.

Health Canada's decision to treat dried marijuana like a drug which must be prescribed, will by consequence require that any medical decisions to prescribe dried marijuana comply with existing legal and regulatory requirements for safe prescribing.

- Included among the requirements applicable to physicians is the fact that physicians are required to evaluate the safety and efficacy of the drug they are considering prescribing.
- It is not clear how physicians could fulfill this requirement. In accordance with Health Canada's own regulatory approval system, dried marijuana is not an approved therapeutic product, due to a lack of evidence regarding safety, efficacy and quality.
- If Health Canada has not approved dried marijuana under its own regulatory processes, due to deficiencies in evidence, it is not clear how Health Canada could legitimately expect that physicians, or other health practitioners, could prescribe dried marijuana in compliance with professional standards and expectations for safe prescribing.

2. Negative Implications for Patients & Physicians

A number of provisions in the draft regulations will have negative implications for both patients and physicians.

- There are insufficient requirements and safeguards in place to ensure patients obtain access to dried marijuana in an appropriate and safe manner. The proposed regulations do not contemplate enabling physicians to check whether a patient: has been registered/de-registered with a licensed producer, or has obtained dried marijuana from another health care practitioner. As such, physicians would not be able to do a comprehensive drug utilization review. Not only could the patient be inappropriately receiving dried marijuana from multiple sources and misusing, abusing or diverting it, the dried marijuana may interact with other treatments, potentially putting patients at risk of harm.

¹ The proposed regulations do not require licensed producers to inform health care practitioners what the THC and CBD content of their product is.



- There do not appear to be any requirements for the licensed producer to import dried marijuana from a producer that has complied with good production practices. Imported dried marijuana must be subject to the same quality and safety standards required for dried marijuana that is produced in Canada. If these same standards do not apply for dried marijuana that is imported, the product may be unsafe for patients.
- Removing Health Canada from the application process makes health care practitioners (namely physicians) the sole decision-makers for determining whether patients can access dried marijuana. In addition, the proposed regulations permit physicians to also sell or provide dried marijuana. Consequently, physicians may feel pressured to prescribe, sell or provide dried marijuana, and may be placed in confrontational situations with their patients. This could negatively affect the physician-patient relationship, and potentially expose physicians and patients to criminal elements and risk.
- The draft regulations will put physicians in a position where they may both prescribe and sell dried marijuana to patients, which may be inconsistent with legal and professional expectations regarding conflicts of interest.
- The requirements proposed for verifying whether the prescription information is complete and accurate do not seem to be sufficient. As such, patients may inappropriately obtain access to dried marijuana without the support of a physician who is permitted to prescribe dried marijuana.
- Under the new program, patients will no longer be able to grow marijuana; only licensed commercial producers will be able to do so. Because licensed producers are able to set the price for dried marijuana, it may result in prices that are unaffordable for some patients.

Given the significance of the concerns outlined above, the CPSO respectfully requests that Health Canada reconsider its approach to reforming the Marihuana Medical Access Program. Health Canada may want to carefully consider alternatives, including the two options outlined in its Executive Summary.

Thank you again for the opportunity to comment. We look forward to working with Health Canada on the proposed changes to the program.

Yours very truly,

Rocco Gerace MD
Registrar

C: Hon. Leona Aglukkaq, Minister of Health