

Guidelines concerning the prescription of dried cannabis for medical purposes

Guidelines

1. The use of dried cannabis for medical purposes is not a recognized treatment.

Despite the rulings of Canadian courts and the existence of medical cannabis access programs, the dried form of this product is not a medically recognized treatment. The indications are not clearly defined, the therapeutic dosages are neither known nor standardized and there is a lack of valid safety data. Information on drug interactions, in particular, is limited.

Despite the insistence of Canada's colleges of physicians, Health Canada and the political authorities of the federal government have adopted regulations under which a prescription is required to obtain dried cannabis for medical purposes. Furthermore, they refuse to have this product undergo the usual licensing process required before a prescription drug can be put on the market. Consequently, the coming into force of these regulations obliges the medical profession to prescribe this product outside the usual framework for prescribing prescription drugs and without the necessary evidence-based scientific data to ensure good medical practice. This creates a unique, unprecedented situation, with certain risks for patients and possible medicolegal implications for the prescribing physician. This situation obliges the Collège to propose a specific, precautionary framework to reconcile compliance with the regulations and the protection of patient health and well-being.

2. According to the *Code of ethics of physicians*, an unrecognized treatment can only be used within a research framework.

In March 2006, the Collège des médecins du Québec published a position statement entitled *The physician and unrecognized treatments* [available in French only].

The principles set out in the position statement have been applied on occasion and will be again here. In accordance with sections 48 and 49 of the <u>Code of ethics</u>, physicians will not be required to prescribe dried cannabis and, as of April 1, 2014, those who agree to prescribe it may only do so within a research framework.

With the collaboration of researchers in Québec, in particular those at the Canadian Consortium for the Investigation of Cannabinoids (CCIC), the Collège is working on developing practical tools that will allow physicians to actively participate in creating a database for research purposes. This database may be used, in particular, in the development of a drug monitoring program.

While allowing the physician to comply with his professional ethics, this initiative should make it possible to:

- systematically collect data on the indications, dosages, benefits or side effects of the products used;
- develop future research;
- ensure safer access to products.
- As of April 1, 2014 and until further notice, only the indications provided for under the access to dried cannabis program of the previous regulations will be considered.

The physician must limit the potential indications to those described for health care professionals on Health Canada's Web site at the following address: http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php#chp40

These indications are listed in Appendix 1 at the end of this document.

A physician may not prescribe cannabis for recreational purposes.

- 4. Before considering the use of dried cannabis to treat a medical condition provided for in the previous regulations, other therapeutic options must be considered, in particular other forms of cannabinoids (tablets or sprays, nabiximols [Sativex®], nabilone [Cesamet®] and dronabinol [Marinol®]) authorized for prescription by Health Canada.
- 5. A physician who is asked to prescribe dried cannabis must:
- read the medical literature;
- inform the patient that dried cannabis is not a recognized treatment and that, in Quebec, it can only be prescribed within a research framework;
- ask him to read the patient information document;
- inform the patient about the research database project or other research projects in progress.

Until the research database is established, a physician who is considering prescribing dried cannabis is asked to keep a register of the patients concerned so that they can be invited to participate in research.

6. Before prescribing dried cannabis, the physician must:

- obtain the written consent of the research participant, have him sign the relevant consent form and enter it in the record:
- carry out a complete medical assessment of the participating patient, complete the assessment and follow-up form that will be available on the Collège des médecins du Québec's Web site and, once it has been completed, enter it in the patient's record.

The purpose of this assessment is to:

- check the indication;
- evaluate the risk of dependence and the risks and benefits of dried cannabis;
- check the possibility of alternative solutions to the use of dried cannabis, in particular other forms of cannabinoids;
- check for the presence of contraindications or interactions with other drugs.

The documents and forms are or will be available at the following address: www.cmq.org, keyword: Cannabis.

7. When a physician prescribes dried cannabis, he must:

- a) specify the type of product, the quantity and the frequency of use on the prescription;
- b) give the patient recommendations for use in situations where alertness is required and could be impaired, e.g., professional activities or driving a motor vehicle;
- c) send the original prescription directly to the producer selected and authorized by Health Canada (producers: http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/list-eng.php), give a copy of the prescription to the patient and enter one in his record;
- d) plan and provide follow-up for the patient in accordance with the assessment and follow-up form;
- e) adjust the prescription accordingly, as needed. The patient must be seen every three months once his condition has stabilized;
- f) keep a register of all patients for whom he has prescribed dried cannabis and, on request, make it available to an officer of the Collège des médecins du Québec.

- 8. Notwithstanding the authorization provided for in the federal regulations, a physician may not supply the patient directly with dried cannabis or deal in cannabis or cannabinoids.
- 9. A physician may not become or apply to become a cannabis producer.
- 10. A physician who prescribes dried cannabis must collaborate with the Collège des médecins and its partners in the collection of scientific data in order to improve knowledge and practices with respect to the use of cannabis for medical purposes and to ensure patient safety.

Appendix 1

As of April 1, 2014 and until further notice, only the indications provided for under the access to dried cannabis program of the previous regulations must be considered:

Conditions and symptoms

	SEVERE PAIN AND NEUROPATHY	PERSISTENT MUSCLE SPASMS	CACHEXIA	Anorexia	WEIGHT LOSS	Severe NAUSEA	Seizures
MULTIPLE SCLEROSIS	√	√					
SPINAL CORD INJURY	√	√					
SPINAL CORD DISEASE	√	√					
CANCER	√		√	√	√	√	
AIDS, HIV	√		√	√	√	V	
SEVERE ARTHRITIS	√						
EPILEPSY							√
PALLIATIVE CARE					1		ı

Source: Health Canada, Form B1