Marihuana for Medical Purposes in Canada: Research, Education and Resourcing

Submitted by: Cannmart Every day thousands of Canadians across the country rely on marihuana (cannabis) as a medicine. Many use it as a last resort to alleviate pain from serious diseases such as cancer or arthritis when other prescription medications are not effective enough or when they cannot tolerate the side effects. Others use it to counteract excessive weight loss and poor appetite related to chronic illness or to improve sleep, and control muscle spasms brought on by illnesses such as multiple sclerosis. An increasing number of Canadians also use cannabis to help manage neurological diseases such as epilepsy.

Canada is one of the few countries that has authorized marihuana for medical purposes on a national basis. However, although Health Canada has been granting patients access to marihuana for medical purposes for numerous health conditions since 2001, recent changes to the system have highlighted new challenges and opportunities for the government to help ease the suffering for Canadian patients.

In order to address the challenges and opportunities, Cannmart is recommending the government take a three pronged approach related to the use of marihuana for medical purposes:

- Support clinical research on marihuana for specific illnesses
- Encourage and support education for physicians and other healthcare professionals
- Increase resourcing for Health Canada to effectively manage the MMPR program

Clinical Research

Modern medicine has succeeded in improving and extending the lives of Canadians based largely on a clinical evidence based approach that relies on information generated by randomized clinical trials to prove the safety and efficacy of drugs. Physicians base their decisions for treatment on the results of these trials. This research is critical for decision making by physicians for the various strains of cannabis for their patients just as it is critical for other approved pharmaceutical products. To date, much of this clinical research has been conducted with patients to demonstrate the positive effects that marihuana can have for people who are suffering various forms of pain. These studies have definitively demonstrated that the active ingredients in cannabis provide significant relief to patients (1-14).

That said, while some clinical research is being done in other areas where cannabis may be effective — for example the use of CBD (one of the active ingredients in cannabis) in treating patients diagnosed with mental illness such as schizophrenia (15-16)— most studies showing therapeutic potential for other illnesses have only been conducted in laboratory tissue or in animals. What is needed now are clinical trials involving human subjects to fully study the medicinal benefits of various cannabis strains in order to confirm the anecdotal evidence given by thousands of Canadian patients.

As previously noted, because of our national program providing access to medical cannabis, Canada is in a unique position to become a world leader in clinical research in the field of cannabinoids - the active ingredients in the cannabis plant. This research would not only serve to confirm therapeutic utility but also to provide much-needed prescribing information to physicians who wish to authorize use of specific strains of cannabis for their patients but have concerns about the lack of research in humans.

The College of Family Physicians of Canada (CFPC) and the Canadian Medical Association (CMA), along

with many of their provincial counterparts have stated there is a need for more clinical research to support the new rules in the *Marihuana for Medical Purposes Regulations* (MMPR) that require physicians to authorize the use of cannabis in order for patients to gain access. The president of the CMA explicitly stated in a recent release: "...asking physicians to prescribe a substance that has not been clinically tested runs contrary to our training and ethics." (17)

The MMPR regulatory changes that were introduced last spring have help set the table for furthering this type of clinical research by allowing any number of cannabis strains to be grown and distributed by licensed producers approved by the Government of Canada. As more licensed producers (LPs) are approved by the government to produce and distribute marihuana for medical purposes, we have the rare opportunity to create strong partnerships between like-minded companies, academic institutions and various government agencies to undertake the needed clinical research in this area.

Cannmart is requesting that the government take this opportunity to invest \$10 million over two years to set up a collaborative, cross-LP research fund to identify further clinical indications for the use of marihuana for medical purposes. Cannmart recommends that this investment be funded through the Canadian Institutes for Health Research (CIHR) or a similar academic oversight body and could be structured as a dollar for dollar match to industry funding.

Continuing Medical Education

Inherently tied to research is a need for continuing medical education for physicians. It is evident that doctors are firm in their belief that more research must be conducted, which would be addressed by our first recommendation. However, as noted, there already exists a wealth of clinical research in the area of cannabinoids for pain relief.

In order to ensure that patients continue to have access while healthcare professionals receive up to date information they need to responsibly authorize marihuana use by their patients, Cannmart is requesting that the Government of Canada support the creation of a continuing medical education (CME) program that would bring healthcare professionals up to date on the current research and best practices in the field of cannabinoids for pain related disorders. Continuing medical education programs are widely used and supported by the CFPC and CMA and are a helpful tool to speak to physicians in a familiar and recognized format.

This CME program would ensure that current research and supporting evidence for the use of cannabis for pain related disorders could be put into an appropriate format and forum for Canadian physicians. This would serve as an important step in gaining support for MMPR to help Canadian patients by the medical community.

Additionally, as further clinical research is performed and results published, other continuing medical education programs could be created to ensure that any and all information regarding the use of cannabinoids for other purposes would be communicated to physicians in a professional and timely manner.

Cannmart is recommending that the government invest \$500,000 in Budget 2015 for an initial continuing medical education program related to the use of marihuana for medical purposes to treat pain. Given the company's expertise in this area Cannmart will be able to put its human resources towards the implementation of this program in collaboration with other LPs in the industry.

Health Canada Resourcing

The introduction of the *Marihuana for Medical Purposes Regulations* has also created a significant resourcing challenge for Health Canada. While applications to become a licensed producer initially came in at a relatively stable rate last fall, that number has now ballooned to over 800 applications with only 13 showing as approved on the department's website.

It has become increasingly evident that Health Canada simply does not have accesses to the resources it needs to complete their review of these applications in a timely and effective manner. This also does not account for future needs of the program as inspections and audits of facilities will need to be maintained as renewal of licensing needs to take place.

The Government of Canada has demonstrated a unique understanding of business needs throughout the last several years. The introduction of the Red Tape Commission and the release of its final report, along with the introduction of programs and tax incentives to assist companies through the economic crisis have demonstrated that Canada is open for business. Unfortunately, Canadian businesses who have been trying to get up and running under the MMPR have been facing great challenges despite the government's efforts. The lengthy timelines and delays that have been faced due to under-resourcing at Health Canada have placed a significant strain on qualified Canadian start-up businesses that are in a delicate position when it comes to funding and financing.

Cannmart recommends that the government immediately reallocate funding to improve resourcing for the Controlled Substances and Tobacco Directorate at Health Canada for the MMPR in order to improve services for LPs and companies waiting for approval of their licenses.

Conclusion

Many countries around the world are beginning to realize the potential for use of marihuana for medical purposes to help their citizens while controlling increasing health care system costs. Canada has the potential to develop a thriving new economic growth engine based in science and to become a leader in this burgeoning field.

Investments in research and education will solidify our country as a leader and innovator and encourage important investments that will help build and improve Canada's economy. Additionally, by ensuring there are sufficient resources within Health Canada to move this program forward, the government will reinforce its commitment to cutting red tape and other impediments for the creation of new businesses.

Cannmart looks forward to working with the government on these recommendations.

About Cannmart

Cannmart is a Canadian start-up company based in Toronto that has applied for a license under the federal *Marihuana for Medical Purposes Regulations*. The company has developed a novel approach in the industry by focusing on the needs of the patient through the development of partnerships with producers from across the country. The company will focus on physician and patient education for the authorization of a variety of the highest quality cannabis strains for treating various and serious ailments, provided by Cannmart.

While Cannmart's producer partners focus on what they do best, Cannmart will reach out to the medical community to provide education on appropriate use of the various strains for cannabis through one-one-one education and accredited continuing education programs and seminars. Cannmart's goal is to provide choice and access to high quality cannabis strains for patients who may benefit from therapeutic use of cannabis under a medical practitioner's care. Cannmart is comprised of former pharmaceutical and medical industry experts and is uniquely positioned to fill this role. Further information about the company can be found online at cannmart.com

References:

- 1. Wang, T. Collet JP, Shapiro S, Ware MA: Adverse effects of medical cannabinoids: a systemic review. CMAJ 2008; 178: 1685-1686
- 2. Izzo, A. A., Borelli, F., Capasso R, Marzo, V and others. Non-psychotropic plant cannabinoids: new therapeutic opportunities from an ancient herb. Trends Pharmacol Sci. 2009; 30: 515-527
- 3. Parker, L. A. Rockm E and Limebeer, C: Regulation of nausea and vomiting by cannabinoids, Bri J. Pharmacol; 2010. 163: 1411-1422
- 4. Zuurman, L, Ippel, AE, Moin E and van Gerven J M. Biomarkers for the effect of cannabis and THC in health volunteers. Br. J. Phrmacol; 2009. 67: 5-21
- 5. Hollister, LE. Health aspects of cannabis: revisited. Int J. Neuropsychopharmacol. 1998. 1: 71-80
- 6. Carter, GT, Weydt, P. Kyasha-Tocha, M. and Abrams, DJ. Medicine cannabis: rational guidelines for dosing. IDrugs, 2004. 7: 464-470
- 7. Thaler, A, Gupta A, Cohen S P: Cannabinoids for Pain Management, Adv Psychosom Med. 2011. 30: 125-138
- 8. Health Canada: Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids. February 2013
- 9. Huestis M A, Human cannabinoid pharmacokinetics, Chem. Biodivers. 2004. 4: 1770-1804
- 10. Blake D, Robson P, Ho M, Jubb RW, McCabe CS: Preliminary assessment of the efficacy, tolerability and safety of a cannabis-based medicine (Sativex) in the treatment of pain caused by rheumatoid arthritis. Rheumatology(Oxford) 2006: 45:50-52
- 11. Hall, W, Solowij J: Adverse effects of cannabis. Lancet 1998; 352: 1611-1616
- 12. Kalant H: Adverse effects of cannabis on health: an update of the literature since 1996. Prog Neuropsychopharmacol Biol Pschiatry 2004. 28: 849-863
- 13. Institute of Medicine (IOM): Marijuana and medicine: assessing the science base. Washington, National Academy Press, 1999.
- 14. Elizabeth J. Rahn and Andrea G. Hohmann: Cannabinoids as Pharmacotherapies for Neuropathic Pain: From the Bench to the Bedside Neurotherapeutics. 2009 October; 6(4): 713–737

- 15. Leweke, FM; Piomelli D, Pahlisch F, Muhl D, Gerth CW, Hoyer C, Klosterkötter J, Hellmich M and Koethe D. (2012). "Cannabidiol enhances anandamide signaling and alleviates psychotic symptoms of schizophrenia". *Translational Psychiatry* 2 (3): e94–. doi:10.1038/tp.2012.15.
- 16. <u>Cannabidiol as a potential treatment for psychosis.</u> Schubart CD, Sommer IE, Fusar-Poli P, de Witte L, Kahn RS, Boks MP.Eur Neuropsychopharmacol. 2014 Jan;24(1):51-64. doi: 10.1016/j.euroneuro.2013.11.002. Epub 2013 No
- 17. It's high time for Canadian Medical Association to get with the medicinal pot program, Breakenridge, David, Calgary Sun, 2014.04.12