

CMA submission:

PROPOSED APPROACH TO THE REGULATION OF CANNABIS

Submission to Health Canada

January 19, 2018

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, the CMA's mission is empowering and caring for patients, with a vision for a vibrant profession and a healthy population.

On behalf of its more than 85,000 members and the Canadian public, the 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 over 60 national medical organizations.

Introduction

The Canadian Medical Association appreciates this opportunity to respond to Health Canada's public consultation on the proposed regulatory approach for the proposed *Cannabis Act*, Bill C-45.

Our approach to cannabis is grounded in broad public health policy. It includes promotion of health and prevention of drug dependence and addiction; access to assessment, counselling and treatment services; and a harm reduction perspective. The CMA endorsed the Lower-Risk Cannabis Use Guidelines¹ and has expressed these views in our recommendations to the Task Force on Cannabis Legalization and Regulation,² recommendations regarding Bill C-45³ and submission on the cannabis excise duty framework.⁴

Therefore, we are limiting our response to those consultation questions that pertain to that approach and relate to our expertise and knowledge base. We are providing responses to questions 9, 10 and 11.

Consultation questions

Packaging and labelling

9. What do you think about the proposed rules for the packaging and labelling of cannabis products? Do you think additional information should be provided on the label?

The CMA concurs with the proposed regulations. Packaging and labelling of cannabis products should include measures such as:

- a requirement for plain and standard packaging,^{5 6}
- prohibition of the use of appealing flavours and shapes,
- a requirement for adequate content and potency labelling,
- a requirement for comprehensive health warnings,
- a requirement for childproof packaging, and
- a requirement that the content in a package should not be sufficient to cause an overdose.

Education is required to develop awareness among Canadians of the health, social and economic harms of cannabis use especially in young people. In that regard, the regulations with respect to packaging and labelling should be viewed as an opportunity to maximize educational opportunities. Package inserts must outline and reinforce the health risks involved; they must also be designed by governments and health professionals, not cannabis producers or distributors.

Package inserts should include:

- information on securing the product in the home to prevent access by youth and children,
- recommendations not to drive or to work with hazardous chemicals or operate equipment while using the contents of the package,
- information on the health and social consequences (including legal penalties) of providing cannabis to those under a designated minimum age for purchasing, and
- contact information for hotlines for poison control and for crisis support.

In addition, the regulations for the marketing and advertising of cannabis should use an approach similar to those in place for tobacco and cigarettes.^{7 8 9}

Cannabis for medicinal purposes

10. What do you think about the proposed approach to providing cannabis for medical purposes? Do you think there should be any specific additional changes?

CMA maintains its position that there should be one system with one set of regulations for medical and recreational cannabis.

The CMA believes that once the Act and regulations are in force, there will be no need for two systems. Cannabis will be available for those who wish to use it for medicinal purposes, either with or without medical authorization, and for those who wish to use it for other purposes. The medical profession does not need to authorize use once cannabis is legalized, especially given that cannabis has not undergone Health Canada's usual pharmaceutical regulatory approval process, and its anticipated removal as a controlled substance from the *Controlled Drugs and Substances Act*.

Those who have experienced a two-system approach in Washington and Colorado have remarked on the challenges of having dual standards and regulations (e.g., purchase and possession quantities, taxation levels^{a 4}) and the contribution to the grey market.^{b 10}

Consistent with the advice it received from the Task Force on Legalization and Regulation of Cannabis,¹¹ the government intends on pursuing both a medicinal and retail cannabis system at this time. In this instance the CMA supports regulations for each system being as similar as possible. Furthermore, the CMA strongly supports the need for appropriate and relevant data collection (e.g., interaction of individuals between the medicinal and retail systems) to provide the necessary evidence for the future legislative review, anticipated in three years' time. The CMA would expect to be involved and looks forward to participating in the criteria development, evaluation and performance review of the systems.

Sale of health products containing cannabis

11. What do you think about the proposed restrictions on the sale of health products containing cannabis authorized by Health Canada? Do they strike an appropriate balance between facilitating access to safe, effective and high quality health products, and deterring illegal activities and youth access?

Health products include prescription health products, non-prescription drugs, natural health products, cosmetics and medical devices. Although all these products are regulated by Health Canada, they undergo different levels of scrutiny for safety, efficacy and quality, and in some cases industry does not need to provide scientific evidence to support the claims made on the label. The level of proof required to obtain a Drug Identification Number (DIN) for prescription drugs is considerably higher than the level of proof required for a Natural Product Number (NPN); rigorous scientific evidence is needed for a DIN but not for a NPN. Consumers generally do not know about this distinction, believing that Health Canada has applied the same level of scrutiny to the health claims made for every product. As a result, consumers presently do not have sufficient information to choose appropriate products.

Health Canada launched a consultation in 2016¹² on the approval process of the categories of non-prescription drugs, natural health products and cosmetics ("self-care products") with the intent of modernizing the present regulations. The CMA fully supports this work and hopes it will be brought to a timely conclusion.¹³

With respect to all health products, the CMA supports a risk-based approach in which higher risk products, for example, those for which health claims are made, must meet a higher standard of review. Rigorous scientific evidence is needed to support claims of health benefits and to identify potential risks and adverse reactions.

All health products containing cannabis must meet a high standard of review for safety, efficacy and

^a The CMA supports similar taxation treatment of cannabis products for medical and non-medical purposes.

^b Grey market refers to products produced or distributed in ways that are unauthorized or unregulated, but not strictly illegal.

quality, equivalent to that of the approval of prescription drugs (e.g., Marinol® and Sativex®), to protect Canadians from further misleading claims. Prescription drugs are subject to Health Canada's pharmaceutical regulatory approval process, based on each drug's specific indication, dose, route of administration and target population. Health claims need to be substantiated via a strong evidentiary process.

With respect to the sale of cannabis products to youth, the CMA recommends the adoption of strict controls as outlined in the proposed regulations; as per the proposal, "All health products would be subject to provisions that control against practices that may appeal to youth, or the use of testimonials, real or fictional characters or animals, or lifestyle branding. Tamper-evident and child-resistant packaging requirements would also apply."¹⁴ We also support the additional precautions around medical devices, especially those sold to young persons.

The CMA urges caution around the exemption for paediatric formulations that would allow for traits that would "appeal to youth." The CMA understands that these products, used under strict health professional supervision, should be child friendly, for example, regarding palatability, but we do not support marketing strategies that would suggest their use is recreational (e.g., producing them in candy or animal formats).

There will be a need for careful monitoring of the health products released in the market and the health claims made. Experience has shown that regulations can and will be circumvented, and these activities will have to be addressed. Various examples have been reported in the media highlighting the need to be vigilant, as illustrated in Switzerland regarding health and other products with cannabis and high cannabidiol content.^{15 16}

¹ Fischer B, Russell C, Sabioni P, et al. Lower-risk cannabis use guidelines: A comprehensive update of evidence and recommendations. *AJPH* 2017 Aug;107(8):e1-e12. Available: http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.303818?url_ver=Z39.88-2003&rft_id=ori%3Arid%3Aacrossref.org&rft_dat=cr_pub%3Dpubmed& (accessed 2017 Jul 27).

² Canadian Medical Association (CMA). *Legalization, regulation and restriction of access to marijuana. CMA submission to the Government of Canada – Task Force on cannabis, legalization and regulation*. Ottawa: The Association; 2016 Aug 29. Available: www.cma.ca/Assets/assets-library/document/en/advocacy/submissions/2016-aug-29-cma-submission-legalization-and-regulation-of-marijuana-e.pdf (accessed 2017 Jul 27).

³ Canadian Medical Association (CMA). *Bill C-45: The Cannabis Act. Submission to the House of Commons Health Committee*. Ottawa: The Association; 2017 Aug 18. Available: <http://www.cma.ca/dbtw-wpd/Briefpdf/BR2017-09.pdf> (accessed 2018 Jan 17).

⁴ Canadian Medical Association (CMA). *Excise duty framework for cannabis products. Submission to the Government of Canada consultation on the proposed excise duty framework for cannabis products*. Ottawa: The Association; 2017 Dec 7. Available: <http://www.cma.ca/dbtw-wpd/Briefpdf/BR2018-06.pdf> (accessed 2018 Jan 17).

⁵ Vardavas C, Filippidis F, Ward B, et al. Plain packaging of tobacco products in the European Union: an EU success story? *European Respiratory Journal* 2017;50:1701232 Available: <http://erj.ersjournals.com/content/erj/50/5/1701232.full.pdf> (accessed 2018 Jan 17).

⁶ Torjesen I. Standardised packs cut adult smoking as well as discouraging young people, evidence indicates *BMJ* 2015;350:h935. Available: <http://www.bmj.com/content/350/bmj.h935> (accessed 2018 Jan 17).

⁷ Hughes N, Arora M, Grills N. Perceptions and impact of plain packaging of tobacco products in low and middle income countries, middle to upper income countries and low-income settings in high-income countries: a systematic review of the literature. *BMJ Open* 2016;6:e010391. doi:10.1136/bmjopen-2015-010391. Available: <http://bmjopen.bmj.com/content/bmjopen/6/3/e010391.full.pdf> (accessed 2018 Jan 17).

⁸ White V, Williams T, Wakefield M. Has the introduction of plain packaging with larger graphic health

warnings changed adolescents' perceptions of cigarette packs and brands? *Tob Control* 2015;24:ii42–ii49. Available: http://tobaccocontrol.bmj.com/content/tobaccocontrol/24/Suppl_2/ii42.full.pdf (accessed 2018 Jan 17).

⁹ Smith C, Kraemer J, Johnson A, Mays D. Plain packaging of cigarettes: do we have sufficient evidence? *Risk Management and Healthcare Policy* 2015;8:21-30. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4396458/pdf/rmhp-8-021.pdf> (accessed 2018 Jan 17).

¹⁰ Canadian Centre on Substance Use and Addiction (CCSA). *Cannabis regulation: Lessons learned in Colorado and Washington State*. Ottawa: CCSA; 2015 Nov. Available: <http://www.ccsa.ca/Resource%20Library/CCSA-Cannabis-Regulation-Lessons-Learned-Report-2015-en.pdf> (accessed 2018 Jan 18).

¹¹ Task Force on Cannabis Legalization and Regulation. *A framework for the legalization and regulation of cannabis in Canada: final report*. Ottawa: Health Canada; 2016. Available: <https://www.canada.ca/content/dam/hc-sc/healthy-canadians/migration/task-force-marijuana-groupe-etude/framework-cadre/alt/framework-cadre-eng.pdf> (accessed 2018 Jan 18).

¹² Government of Canada. *Consultation on the regulation of self-care products*. Ottawa: Government of Canada; n/d. Available: <https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products.html> (accessed 2018 Jan 17).

¹³ Canadian Medical Association (CMA). *Regulation of self-care products in Canada*. Ottawa: The Association; 2016. Available: <http://www.cma.corp/dbtw-wpd/Briefpdf/BR2017-11.pdf> (accessed 2018 Jan 17).

¹⁴ Health Canada. *Proposed approach to the regulation of cannabis [consultation]*. Ottawa: Health Canada; 2017 Nov. Available: <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-proposed-approach-regulation-cannabis/proposed-approach-regulation-cannabis.pdf> (accessed 2018 Jan 17).

¹⁵ Knodt M. In Switzerland, high-CBD cannabis being sold legally as 'Tobacco Substitute'. Seattle: Leafly; 2018. Available: <https://www.leafly.com/news/politics/switzerland-high-cbd-cannabis-sold-legally-tobacco-substitute> (accessed 2018 Jan 17).

¹⁶ Wiley C. Could a legal quirk bring cannabis tourism to Switzerland? *The Telegraph* 2017 Jul 28; Travel Section. Available: <http://www.telegraph.co.uk/travel/destinations/europe/switzerland/articles/cannabis-tourism-has-arrived-in-switzerland/> (accessed 2018 Jan 17).