

CMA response:

HEALTH CANADA CONSULTATION ON
POTENTIAL MARKET FOR CANNABIS
HEALTH PRODUCTS THAT WOULD
NOT REQUIRE PRACTITIONER
OVERSIGHT

September 03, 2019

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, the CMA's mission is to empower and care for patients and its vision is to support 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.

The Canadian Medical Association (CMA) appreciates this opportunity to respond to Health Canada's consultation on potential markets for cannabis health products that would not require practitioner oversight.¹

The CMA's approach to cannabis is grounded in public health policy. It includes promotion of health and prevention of problematic use; access to assessment, counseling and treatment services; and a harm reduction perspective. The CMA endorsed the Lower-Risk Cannabis Use Guidelines² and has expressed these views in our recommendations to the Task Force on Cannabis Legalization and Regulation,³ and recommendations regarding Bill C-45.⁴ As well, we submitted comments to Health Canada with respect to the consultation on the proposed regulatory approach for the *Cannabis Act*, Bill C-45.⁵ We also responded to Health Canada's recent Consultation on Edible Cannabis, Extracts & Topicals.⁶

Overview

The CMA first expressed its concerns about the sale of natural health products containing cannabis in our response to the proposed regulatory approach to the *Cannabis Act*, Bill C-45.⁵ We recognize that, in general, 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 are subject to 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.

Health Claims

As with all health products, the CMA supports an approach in which higher risk products, that is, those for which health claims are made, must be subject to a more meticulous standard of review. Rigorous scientific evidence is needed to support claims of health benefits and to identify potential risks and adverse reactions.

We support Health Canada's proposal that authorized health claims for cannabis health products (CHP) would be permitted for treatment of minor ailments, on the strict condition they are substantiated via a strong evidentiary process. It is the view of the CMA that all such products making a health claim must be reviewed thoroughly for efficacy, as well as safety and quality, for the protection of Canadians.⁵

Recent experience in the United States supports this approach. A warning letter was sent to Curaleaf Inc. of Wakefield, Massachusetts, by the US Food and Drug Administration (FDA) "for illegally selling unapproved products containing cannabidiol (CBD) online with unsubstantiated claims that the products treat cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety, among other conditions or diseases."⁷

This is not the first time it was necessary for the FDA to take such action. The agency had sent letters on previous occasions to other businesses over claims "to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the Federal Food, Drug and Cosmetic Act because they were marketed as dietary supplements or because they involved the addition of CBD to food."⁷

The CMA shares the FDA's concerns that such claims "can put patients and consumers at risk by leading them to put off important medical care."⁷ A study conducted by Dalhousie University found that only 35.8% of respondents were familiar with the biochemical properties of CBD when asked what cannabinoid they thought was potentially a pain killer.⁸ Systematic reviews and guidelines have highlighted the state of the science and the limited indications for which there is evidence.^{9,10,11}

Both cannabis and CBD specifically have been approved for use in a few conditions, but more research is needed in this rapidly growing field. For example, medical cannabinoids have been approved in several jurisdictions for the treatment of multiple sclerosis but the evidence of how well it works is limited. As the Canadian authors note, "carefully conducted, high-quality studies with thought given to the biologic activity of different cannabis components are still required to inform on the benefits of cannabinoids for patients with MS."¹² Consumers need to be reassured that health claims are being assessed thoroughly so they can make informed decisions.¹³

Packaging and Labelling Requirements

The CMA has laid out its position with respect to packaging and labelling with respect to cannabis products.^{5,6} Strict packaging requirements are necessary as their wider availability raises several public health issues, not the least of which is ingestion by young children. Requirements for tamper-resistant and child-proof containers need to be in place to enhance consumer safety. To reiterate:

- a requirement for plain and standard packaging
- 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 a poisoning

Prescription Drugs Containing Cannabis

The CMA addressed prescription drugs containing cannabis in a previous brief.⁵ 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 to support claims of efficacy is needed for a DIN but not for an 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 enough information to choose appropriate products.

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. All potential prescription medications containing cannabis must meet a high standard of review for safety, efficacy and quality, equivalent to that of the approval of prescription drugs (e.g., Marinol® and Sativex®), to protect Canadians from further misleading claims.

The CMA urges caution especially around exemptions 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).

Recommendations

1. The CMA recommends that all cannabis health products, including those with CBD, making a health claim must be reviewed thoroughly for efficacy, as well as safety and quality, for the protection of Canadians.
2. The CMA recommends that strict packaging requirements be put in place with respect cannabis health products as their wider availability raises several public health issues, not the least of which is ingestion by young children.
3. The CMA recommends tamper-resistant and child-proof containers need to be in place to enhance consumer safety.
4. The CMA recommends that all potential prescription medications containing cannabis must meet a high standard of review for safety, efficacy and quality, equivalent to that of the approval of prescription drugs to protect Canadians from further misleading claims.

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