

CMA response:

HEALTH CANADA CONSULTATION ON EDIBLE CANNABIS, EXTRACTS & TOPICALS

February 20, 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 appreciates this opportunity to respond to Health Canada's consultation on the proposed regulations for edible cannabis, cannabis extracts, and cannabis topicals.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, counselling 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 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

Canada's physicians have a longstanding concern about the health risks associated with consuming cannabis.^{6,7} Consumers use these products for both recreational and medical purposes, compelling the need for accuracy in the labeling as well as quality control in the manufacturing process.¹⁰

Cannabis Edibles, Extracts and Topicals

Cannabis will have a different effect on the user, depending on whether it is smoked or ingested, as in an edible. It has been found that "smoking marijuana results in clinical effects within 10 minutes, peak blood concentrations occur between 30 and 90 minutes, and clearance is complete within 4 hours of inhalation. Oral THC does not reach significant blood concentration until at least 30 minutes, with a peak at approximately 3 hours, and clearance approximately 12 hours after ingestion."⁸ Because of the delay in absorption when ingested, people might consume more to feel the psychoactive effects faster. This might lead to the consumption of very high doses and result in toxic effects, such as anxiety, paranoia and in rare cases, a psychotic reaction with delusions, hallucinations, incoherent speech and agitation.

Rates of use of edibles are not well known. A recent study in California high schools found that "polyuse via multiple administration methods was a predominant pattern of cannabis use and report the first evidence, to our knowledge, of triple product polyuse of combustible, edible, and vaporized cannabis among youths."⁹

We are limiting our response to Health Canada's consultation questions that pertain to the CMA's position with respect to cannabis and relate to our expertise and knowledge base.

Proposed THC limits for the new classes of cannabis products

Standardization within all classes of cannabis products in a legal regime is essential. Tetrahydrocannabinol (THC) levels in black market products can vary widely so one can never be assured of the strength being purchased, creating the potential for significant harm.^{10,11}

Experience in jurisdictions where cannabis has been legalized has shown that restrictions on the potency of products (i.e., THC limits) are necessary, given the higher risks of harm associated with higher potencies.² Prohibition of high potency products is important.³

THC limits should be based on the best available evidence of safety for consumers. The increased potency of cannabis over the years raises concerns about its use in edibles, extracts and topicals, offering a significant challenge with respect to regulating their use.¹² This becomes particularly worrisome with respect to preadolescents and adolescents who should avoid using cannabis due to concerns with the impact on the developing brain.² Use has been associated with a "significant increased risk of developing depression or suicidality in young adulthood."¹³

More research is needed with respect to the effects of cannabis on all age groups, especially children, adolescents and seniors. Saunders et al describe the case of an elderly patient with a history of coronary artery disease suffering what appears to have been a myocardial infarction after ingesting most of a marijuana lollipop that contained 90 mg of THC.¹⁴ Such cases demonstrate how crucial it is to establish appropriate levels of THC. This is an especially important consideration because "consuming cannabis-infused edibles may inadvertently result in toxicity because absorption can take hours, compared with minutes when smoking. An individual who does not yet feel an effect may over-consume."¹⁵

Small children and people with cognitive impairment will not be able to read labels, so preventive measures are very important, as with any pharmaceutical. Since legalizing cannabis, Colorado's Rocky Mountain Poison & Drug Center has reported an increase in calls related to edible exposures.¹⁶ Children can accidentally eat products that contain cannabis, making them ill enough to seek medical assistance.

The CMA maintains that the proposed draft regulations of 10 mg per discrete unit and package is too high and should be established at a maximum of 5 mg per dose, given the higher risks of overconsumption with edibles, the risks of accidents in children and the experience in other jurisdictions. Colorado's limit was set at 10 mg per unit, and health authorities recognize that a lower limit would have been warranted to prevent more accidents.¹⁷ Other preventive measures, such as child proof packaging, are considered in other sections of this brief.

The amount of THC must be displayed clearly and prominently on the package to help prevent accidental or overconsumption of the product.

Rules addressing the types of ingredients and additives that could be used in edible cannabis, cannabis extracts, and cannabis topicals appropriately address public health and safety risks while enabling sufficient product diversity

The CMA concurs with the proposed regulations. Experience in areas such as caffeinated, high-sugar alcoholic beverages provides ample evidence to proceed with restraint concerning the types of ingredients and additives that may be permitted in edible cannabis, cannabis extracts, and cannabis topicals.¹⁸

Proposed new rules for the packaging and labelling of the new classes of cannabis products

The CMA reiterates its position with respect to the packaging and labelling of cannabis products as presented in its submission on the proposed approach to the regulation of cannabis.⁵ This includes:

- 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 an overdose.

Plain and standardized packaging is necessary with respect to edibles as their wider availability raises several public health issues, not the least of which is ingestion by young children. It is imperative that the packages and labels of edibles not resemble popular confectionaries, for example. As the Canadian Paediatric Society has noted, "the unintended consumption of edibles manufactured to look like sweets by younger children is particularly concerning."¹⁵ Also, by "restricting the extent to which marijuana edibles can look and taste like familiar sweets, (it) could also keep the psychological barriers to marijuana initiation among children and adolescents from being lowered."¹⁹ The CMA has adopted similar positions with respect to tobacco and vaping products.^{20,21,22}

It is recognized that these regulations are targeted at products meant for the adult market, but the entry of these new classes also creates challenges beyond that audience. Teens are attracted to vaping cannabis rather than smoking it because "smoke is not combusted and also may allow for more covert use given the reduction in odor."^{23,24} As well, as "edibles have no odor, they are largely undetectable to parents."²³

The CMA views this as an opportunity to educate Canadians about the health, social and economic harms of cannabis especially in young people. 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.

Inserts should include:⁵

- 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.

Cannabis topicals, as outlined in the proposed regulations, would fall under the category of health products and be found in non-prescription drugs, natural health products, and cosmetics. The CMA believes that all health claims need to be substantiated with sufficient evidence that meets standards for efficacy, besides safety and quality, to protect Canadians from misleading claims.⁵ This is important because 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 for effectiveness 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.⁵

Requirements for tamper-resistant and child-proof containers need to be in place to enhance consumer safety. More research is required to address the environmental concerns with extra packaging, which would result from single dose packaging. It is critical to put in place measures that make it difficult to ingest large doses of THC. Simply adding grooves to chocolate bars or baked goods, for example, separating different doses, is insufficient to prevent people, particularly children, from ingesting more than a dose (which in of itself is designed for an adult). As well, there is no guarantee that the THC is spread out uniformly throughout the product.

More research is needed with respect to “determining risks and benefits through proper clinical trials;” that includes determining the safest level of THC for extracts and topicals to reassure consumers will not be harmed by these products.¹⁸

With regards to cannabidiol (CBD), it would seem that “published data from around the world has taught us that misleading labels as well as harmful contaminants are real and actual problems for CBD products.”¹⁸ Health claims need to be substantiated via a strong evidentiary process. There will be a need for careful monitoring of the health products released in the market and the health claims made.⁵ Experience has shown that regulations can and will be circumvented, and these activities will have to be addressed.

Edible cannabis and the requirement for all products to be labelled with a cannabis-specific nutrition facts table

Yes. The CMA supports the use of a cannabis-specific nutrition facts table (NFT) as described in the proposed regulations.¹ These products should have the same standards and regulations applied to them as traditional food products do under the *Food and Drugs Regulations*. As such, a cannabis-specific nutrition facts table will help consumers differentiate them from standard food products.

The proposal for the labelling of small containers and the option to display certain information on a peel-back or accordion panel

The size of the container should not be an impediment to supplying consumers with the necessary information to make informed choices. Manufacturers should be required to use whatever method (peel-back or accordion panel) is most efficient and conveys all the necessary information. As the CMA noted in a recent brief with respect to tobacco labeling the “amount of space given to the warnings should be sufficient to convey the maximum amount of information while remaining clear, visible, and legible. The warnings should be in proportion to the packaging available, like that of a regular cigarette package.”²⁰ Adding warnings on individual cigarettes, as we recommended, illustrates that it is feasible to apply important information to even the smallest surfaces.²⁰

It is important to note that key information should be visible on the external part of the container, including the standardized cannabis symbol, ingredients and warnings.

Proposal that the standardized cannabis symbol would be required on vaping devices, vaping cartridges, and wrappers

Yes. As noted earlier, the CMA called for strict packaging requirements around both tobacco and vaping products.²² The requirement for the standardized cannabis symbol is an extension of that policy and to the labelling of cannabis products in general.⁵

Proposed new good production practices, such as the requirement to have a Preventive Control Plan, appropriately address the risks associated with the production of cannabis, including the risk of product contamination and cross-contamination

Yes. The CMA concurs with this requirement.

The requirement that the production of edible cannabis could not occur in a building where conventional food is produced

Yes. The CMA concurs with this requirement. Separate facilities are necessary to prevent cross-contamination for the protection of consumer health and safety.

Conclusion

The CMA supports the federal government's commitment to a three-year legislative review as it affords the opportunity to evaluate the regulations' impact and adjust them as needed. It continues to be important to have good surveillance and monitoring systems, as well as to continue to learn from other jurisdictions where cannabis is legal for recreational purposes.

Public education and awareness must accompany the introduction of new forms of cannabis, emphasizing the risks of accidental ingestion and overconsumption. It should also emphasize the need for safe storage of cannabis products, as well as personal possession limits.

Much more research is needed into the impact of these new classes across all age groups, and into public health strategies that discourage use and increase harm reduction practices. It is fundamental that profit driven commercialization is rigorously controlled through taxation, regulation, monitoring and advertising controls, in a manner that is consistent with a public health approach.

¹ Government of Canada. *Canada Gazette, Part I, Volume 152, Number 51: Regulations Amending the Cannabis Regulations (New Classes of Cannabis)* Ottawa: Health Canada; 2018. Available: <http://www.gazette.gc.ca/rp-pr/p1/2018/2018-12-22/html/reg4-eng.html> (accessed 2018 Dec 22).

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³ 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: CMA; 2016 Aug 29. Available: <https://policybase.cma.ca/en/permalink/policy11954>. (accessed 2019 Feb 01).

⁴ Canadian Medical Association (CMA). *Bill C-45: The Cannabis Act. Submission to the House of Commons Health Committee.* Ottawa: CMA; 2017 Aug 18. Available: <https://policybase.cma.ca/en/permalink/policy13723> (accessed 2019 Feb 01).

⁵ Canadian Medical Association (CMA). *Proposed Approach to the Regulation of Cannabis.* Ottawa: CMA; 2018 Jan 19. Available: <https://policybase.cma.ca/en/permalink/policy13838> (accessed 2019 Feb 04).

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