

## **Consultation on *Potential Market for Cannabis Health Products that Would Not Require Practitioner Oversight***

### **Ontario Public Health Collaboration on Cannabis (OPHCOC)**

The Ontario Public Health Collaboration on Cannabis is a group of professionals from 35 health units who have joined together to promote a comprehensive public health approach to cannabis legalization.

This response paper was developed and supported by a sub-group of the OPHCOC from the following Public Health Units:

Middlesex London Health Unit; Windsor Essex County Health Unit; Kingston, Frontenac, Lennox and Addington Public Health; Perth District Health Unit; Southwestern Public Health; Wellington-Dufferin-Guelph Public Health; York Region Public Health; North Bay Parry Sound District Health Unit; Eastern Ontario Health Unit; Chatham-Kent Public Health; Thunder Bay District Health Unit; Peterborough Public Health; Porcupine Health Unit; Lambton Public Health; Hastings Prince Edward Public Health; Simcoe Muskoka District Health Unit; Public Health Sudbury & Districts; Niagara Region Public Health; Grey Bruce Health Unit; Region of Peel - Public Health

The Ontario Public Health Collaboration on Cannabis (OPHCOC) appreciates the opportunity to participate in Health Canada's consultation on *Potential Market for Cannabis Health Products that would not Require Practitioner Oversight*. The OPHCOC is pleased that public health and safety, while controlling access to safe, effective and quality products are among the key components of the consultation document, the *Health Products Containing Cannabis or for use with Cannabis: Guidance for the Cannabis Act* (guidance document), the *Food and Drugs Act* (FDA) and related regulations framework.

The OPHCOC believes having access to regulated products that are scientifically proven to benefit the health of consumers is favourable, as long as the regulations reflect and support the intent of the *Cannabis Act*, with the priorities being, to prevent youth access and eliminate the illegal market. The OPHCOC recognizes and supports that approval of cannabis health products CHPs will encourage future research to inform public health practices. Further considerations from the OPHCOC are outlined below.

**The OPHCOC recommends alignment with the *Cannabis Act* in regard to providing cannabis to a minor.** We agree that unrestricted access to CHPs by young persons may induce or normalize the use of cannabis. Health Canada's proposition to permit a young person access to CHPs through a responsible adult intermediary runs counter to the objectives of the *Cannabis Act* to protect youth and recommendations from the Canadian Pediatric Society which states that "Overall, there are insufficient data to support either the efficacy or safety of cannabis use for any indications in children, and an increasing body of data suggests possible harm, most importantly in specific conditions."<sup>1</sup> The OPHCOC recommends that CHP regulations align with the *Cannabis Act* so that providing CHPs to a minor would be restricted. Furthermore, restrictions on access should be aligned with provincial/territorial laws regarding age of access. This recommendation is supported by current evidence, including Health Canada's document; [Cannabis and your Health](#), which states that cannabis affects the neurobiological system that is responsible for brain development. We know that individuals exposed to cannabis under the age of 25 are most at risk of cannabis related harms both mentally and physically, due to brain development which takes place through the mid-twenties. In particular, the risk of mental health problems increases with early initiation of cannabis use and heavy, frequent use. These problems include dependence and disorders related to anxiety, depression, psychotic disorders, as well as impairment with learning and memory. Stopping use can help improve these deficits, however, some of these harms may persist for months or years or may become permanent.<sup>2</sup> The OPHCOC believes it is essential that a precautionary approach is taken until further information is known about the long-term impact that tetrahydrocannabinol (THC), cannabidiol (CBD) and other cannabinoids have on the developing brain, across the lifespan, and on vulnerable populations such as youth, and women who are pregnant or breastfeeding.

**The OPHCOC proposes that the regulations prohibit the distribution and access of sample products by or for any party including manufacturers and retailers, healthcare providers, or any individual, or organization.** The OPHCOC supports the requirement proposed in the guidance document that the sale of CHPs follows each province's/territory's current distribution and sale of cannabis products framework and that samples, gifts or free products are not permitted.

**The OPHCOC supports the CHP packaging requirements proposed in the consultation document.** The OPHCOC supports the requirement that all CHP packaging aligns with the *Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products*, FDA health product labeling requirements, and all packaging and labeling requirements under the *Cannabis Act*. The OPHCOC is concerned about individuals self-diagnosing and self-medicating without medical oversight. Regulated labeling requirements will help inform the consumer. The following warnings should be clearly stated on all CHPs:

- Do not use if pregnant or breastfeeding
- Keep out of reach of children and youth
- Seek medical advice for potential drug interactions
- This product should not replace medical advice

To help prevent unintentional consumption, packaging should be in-line with current restrictions under the *Cannabis Act* for plain, child-resistant packaging which does not appeal to youth or children. Packaging should also be consistent with cannabis health warning message regulations.

**The OPHCOC supports the requirement for pre-market approval for safety, efficacy, and quality under FDA, and scientifically rigorous evidence before a health claim can be made or a product is granted access to the market.** We support the recommendation that specific criteria are developed and used to ensure research findings comprise robust, scientific evidence. We are concerned that, if a rigorous scientific evidence-based approach is not enforced, the presence of unsubstantiated health claims can place not only youth and children at risk of harm, but any consumer. Health claims could be misleading for parents, who may unintentionally expose their child to a harmful substance, and misleading to general consumers about the effectiveness of products to treat various ailments. Similar to the current regulations for cannabis products for medical purposes, for which practitioner oversight is necessary, CHPs should also require that manufacturing be subject to quality and security requirements under the *FDA* and *Cannabis Act*.<sup>3</sup>

**The OPHCOC is in support of CHP regulations that align with current Health Canada regulations for edible cannabis, cannabis extracts, and cannabis topicals and cautions the approval of cannabis health food products.** These regulations include: restriction of additives, such as nicotine, caffeine, alcohol, sugar or sweeteners; packaging and labeling regulations, including standardized cannabis symbol and a nutrition facts table when needed; products that do not target or are not intended for children or youth (e.g. vitamin gummies), and; production in facilities that do not produce other health products or food products. The OPHCOC is concerned that food products applying for CHP status will be a way for edible cannabis suppliers to apply a health claim to food products. Health claims on food products can inadvertently encourage consumers to consume not only cannabis products, but also the calorie dense, nutrient poor foods often associated with edible cannabis. The OPHCOC cautions the approval of cannabis health food products, especially products that might appeal to children or youth.

**The OPHCOC recommends a maximum amount of 10ppm of THC in CHPs, as this amount of THC will have little psychoactive effect.**<sup>4</sup> Much is still unknown about cannabinoids and how they affect the body or interact with each other, but THC is associated with many harms, especially in youth because of their developing brain. Due to

the intoxicating effects of THC, products with more than the recommended trace amount of THC could potentially lead to impairment, injuries, psychosis, and other short and long-term harms.<sup>2</sup>

**The OPHCOC recommends prohibiting CHPs which require inhalation in order to achieve the intended effects.** Long-term harms associated with tobacco smoke and second-hand smoke is well known, as well, there is growing knowledge of vaping products and the long-term harm they may cause. We recommend taking a precautionary approach and gather more evidence on the long-term effects of inhalation devices which contain any amount or type of cannabinoid before placing them on the market for use with CHPs.

**The OPHCOC recommends that Health Canada provide clear guidelines and designate enforcement responsibilities for the oversight of CHPs.** To be effective, regulations must be supported through proper communication and enforcement efforts. We recommend clear and extensive guidelines mandating oversight of the production and sale of CHPs. This would include: outlining how enforcement of the production of these products will be effectively and feasibly performed, how the regulations pertaining to the sale and promotion of these products will be enforced, and how scientific evidence will be validated.

Thank you for the opportunity to provide input on the potential market for cannabis health products that would not require practitioner oversight. We would be happy to discuss any of our recommendations or comments upon your request and look forward to the summary from Health Canada following this consultation.

Sincerely,

Sara Tryon

Co-Chair of OPHCOC, representing the OPHCOC sub-group on this consultation

[Sara.tryon@kflaph.ca](mailto:Sara.tryon@kflaph.ca)

Elena Hasheminejad

Co-Chair of OPHCOC, representing the OPHCOC sub-group on this consultation

[Elena.hasheminejad@york.ca](mailto:Elena.hasheminejad@york.ca)

## References

1. Michael J Rieder, (2016) Canadian Pediatric Society. Position Statement: Is the medical use of cannabis a therapeutic option for children? Retrieved August 21, 2019 from: <https://www.cps.ca/en/documents/position/medical-use-of-cannabis>
2. Health Canada. (2019). Cannabis and your health. Retrieved from <https://www.canada.ca/en/services/health/campaigns/cannabis/health-effects.html>
3. Health Canada. (2018). Health Products Containing Cannabis or for use with Cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and Related Regulations. Retrieved from [https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cannabis-health-products-guidance-eng\(2\).pdf](https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cannabis-health-products-guidance-eng(2).pdf)
4. Health Canada. (2017). Proposed Approach to the Regulation of Cannabis. Retrieved from <https://www.canada.ca/en/health-canada/programs/consultation-proposed-approach-regulation-cannabis/proposed-approach-regulation-cannabis.html#a85>