Canadian Centre on Substance Use and Addiction

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Consultation on the Cannabis Regulations: Cannabis Research and Other Regulatory Issues

Introduction

The Canadian Centre on Substance Use and Addiction (CCSA) welcomes the opportunity to provide comment and feedback on Health Canada's *Consultation on the* Cannabis Regulations*: Cannabis research and other regulatory issues*. As we approach the three-year anniversary of cannabis legalization in Canada and the legislated review of the *Cannabis Act*, this consultation provides a meaningful opportunity to examine the impacts of the current regulations. CCSA supports maintaining a public health approach to cannabis regulation based on available evidence, including:

- Amending the current regulations for research on non-therapeutic cannabis to simplify the application process, while protecting participant health and safety;
- Examining further the merits and implications of public possession limits;
- Adjusting labelling requirements to ensure additives, including terpenes, are reflected in the product label, while establishing best practices for communicating THC and CBD levels in an easily understandable manner;
- Maintaining and enforcing restrictions on advertising and promotion of cannabis products, particularly those directed at youth, while potentially strengthening limits to promotional activity in online environments; and
- Expanding public education as a means of reducing potential harms related to higher-risk use of cannabis and use among youth and other high-risk populations.

This submission is informed by available evidence as well as consultation with partners and experts in cannabis research. CCSA's response is focused on areas where we have relevant experience and expertise.

Part 1: Proposed regulations amending the Cannabis Regulations *and associated regulations to facilitate non-therapeutic cannabis research involving human participants and cannabis testing*

CCSA has heard clearly from the research community that the current research licence requirements place barriers to conducting cannabis research, resulting in significant time and resource investment and lengthy delays that in turn cause complications with time-limited funding agreements and delays in making results available to inform policy and practice in a timely manner.

Q2: Should the requirements to conduct non-therapeutic cannabis research involving human participants under the CR [*Cannabis Regulations*] be similar to those that currently apply to clinical trials under the FDR [*Food and Drug Regulations*] (e.g., protocol review by a research ethics board, submission of extensive quality [chemistry and manufacturing] information, review of written informed consent, and submission of an investigator's brochure)? If the requirements should differ, how?

Necessary requirements vary according to the proposed research methodology and design. All research involving human subjects requires approval by a research ethics board. This approval involves a review of research protocols and weighing of potential risks and benefits of participation.

Studies involving the administration of a substance that is legally available for non-therapeutic use have less stringent requirements than those that apply to clinical trials under the *Food and Drug Regulations*. The feedback CCSA has received from the research community is reflected in the following recommendations:

- Align the requirements for non-therapeutic cannabis research with those for research involving other legal substances such as alcohol;
- Remove the requirement for investigators to submit product quality and safety information for testing involving products available to consumers through the legal market, noting that these products must already demonstrate product quality and safety; and
- Revise the requirement for submission of an investigator's brochure, which often requires the researcher to have an agreement with a cannabis producer, creating the potential for industry influence on the research being conducted, as well as real or perceived conflict of interest.

All research involving human participants should continue to adhere to ethical and safe research practices, including protocol review by a research ethics board and obtaining the informed consent of participants.

Q3: Should non-therapeutic research involving human participants be restricted to certain participants (e.g., exclude individuals with previous/current mental health or substance use disorders, age restrictions)?

The type of research being conducted should determine restrictions placed on participant eligibility, including for those with previous or current mental health or substance use disorders. These factors would be taken into account in the process of a research ethics review to ensure an appropriate balance between the risk to participants and the benefit of resulting knowledge.

During an ethics review, reasonable restrictions should be considered on the participation of people:

- Who have a previous or current mental health or substance use disorder (Konefal, Gabrys, & Porath, 2019). Consideration may be given to observational studies looking at the outcomes of cannabis use on people with mental health or substance use disorders that do not introduce or increase risk behaviours;
- Who do not have prior experience of cannabis use;
- Who are below the legal age to purchase cannabis in the jurisdiction in which the research is being conducted; and
- Who have a health condition for which cannabis is counter-indicated (e.g., cardiac and respiratory conditions (Renard, 2020).

The participation of women who are pregnant or breast-feeding should also be restricted (Porath, Konefal, & Kent, 2019).

Q4: Should there be restrictions on the types of cannabis used in non-therapeutic cannabis research involving human participants? If so, under what circumstances? What should the quality requirements be for cannabis derived from synthetic sources?

The products used in non-therapeutic cannabis research should be limited to those legally available through licensed producers or retail outlets, which have met the production and quality standards established in the *Cannabis Regulations.*

Q5: Should there be restrictions on the dosage, frequency, duration and route of administration (e.g., smoking or vaping) of cannabis used in non-therapeutic cannabis research involving human participants?

The relative risks and suitability of different dosages, frequencies, durations and routes of administration will be considered by research ethics boards in light of the nature of the research being conducted. Where possible, administration should not exceed pre-existing patterns of use.

Q6: Should adverse reaction reporting for non-therapeutic cannabis research involving human participants be treated in a similar manner as adverse reaction reporting for clinical trials under the FDR? Why or why not?

We recommend that the reporting of adverse reactions in line with current regulations be maintained to ensure participant well-being, gain a better understanding of potential risks associated with cannabis use, and maintain ethical and safety standards and best practices.

Part 2: Feedback on additional regulatory issues

The objectives of the *Cannabis Act* include protecting public health and safety through product safety and quality requirements, while enhancing public awareness of the health risks associated with cannabis use. Regulations in place that limit public possession of cannabis, as well as product labelling requirements and restrictions on advertising and promotion, are designed to encourage safer cannabis use and to reduce high-risk use. Any adjustments to current regulations should be evidence based and prioritize public health and safety.

Public possession limit

All jurisdictions that have implemented a form of cannabis regulation to date, including the Netherlands, Uruguay and the United States, have applied limits to the quantity allowed for purchase and possession.

The primary function of possession limits is to reduce the diversion of regulated product to the illegal market. Whether this objective is being achieved requires investigation to determine the extent to which regulated product is in fact being diverted to the illegal market and the extent to which police have been able to use the possession limits as a tool with which to intervene in intended diversions.

There are also important questions about whether this tool is being applied equitably, particularly with respect to race and socio-economic status, and whether the impacts are proportional to the benefits given the severity of the consequences of a criminal record. Investigation of these questions is not feasible within the timeframe of the current consultation. However, they will be pursued to inform the legislative review of the *Cannabis Act.*

The second justification for personal possession limits is to discourage higher-risk levels of consumption; for example, through forced rationing. The relationship between quantity and format of purchase and high-risk consumption is another question that is being explored through empirical

research. Relevant to question 11 below, it is important that possession limits do not incentivize the purchase of higher-potency products.

Q9: Do you think the public possession statement on cannabis product labels helps adults comply with the public possession limit?

It is not clear what impact public possession statements on cannabis product labelling has on compliance with regulated limits. This question also requires empirical investigation, which can be undertaken to inform the legislative review.

Q10: Currently, the CR require labels to display a statement to express the amount of cannabis a product is equivalent to in terms of grams of dried cannabis. Do you see any issues with this approach? Are there any benefits or challenges you think an adult may have in interpreting this information on different kinds of cannabis products (e.g., edible cannabis, cannabis topicals, vaping products, etc.)?

Presenting information in this manner assumes a baseline knowledge of dried cannabis among consumers who may not be familiar with dosage equivalents. Evidence has demonstrated a low level of knowledge of standard servings and THC levels, particularly as concerns edibles (Hammond, 2019; Kosa, Giombi, Rains, & Cates, 2017). The dried cannabis equivalency offers the benefit of assisting consumers in staying within personal possession limits, provided they are also aware of those limits. However, a standard dose equivalency would be more informative to consumers from a health and safety perspective in terms of consumption.

Q11: Do you think the current public possession limit for cannabis beverages (which is currently approximately 2 litres) should be increased? If yes, please explain what you think an appropriate public possession limit would be for these products and why.

Current equivalency tables for non-solid cannabis products equate 70 grams of liquid to one gram of dried product or 15 grams of solid product. This practice results in a much lower possession limit for cannabis beverages than if a dose equivalency approach was used.

Volumetric rather than weight-based limits on cannabis beverages would allow for greater alignment with other products. Volumetric limits would still be used in combination with the different product categories based on percentage THC and account for differences in bioavailability and psychoactive effects.

Cannabis beverages are quite new to the market. Continued research to better understand their impacts, such as time to onset and duration of effects, is important from a public health perspective, especially to inform consumer education.

Product labelling

Labelling requirements can help ensure consumers are better informed about product contents. However, research indicates that the current approach does not effectively communicate THC levels and dosage (Hammond, 2019; Goodman & Hammond, 2020; Leos-Toro, Fong, Meyer, & Hammond, 2020). Evidence from research about nutrition labelling indicates there are challenges for consumers in understanding and applying serving size information correctly, particularly among populations with lower literacy levels (Campos, Doxey, & Hammond, 2011).

Q12: Should Health Canada require product labels to display information about other cannabinoids and terpenes (e.g., quantity or concentration)? Why or why not? If yes, which cannabinoids and terpenes and why?

CCSA supports the listing of cannabinoids and terpenes that have been added to a product. We also note that these should be listed in a neutral manner and respect restrictions on making claims to health or other benefits, in accordance with current regulations. The purpose of listing these additions should be consumer information and transparency rather than marketing and promotion. Any additional labelling requirements must not interfere with clear communication of THC and CBD.

Guidelines from Health Canada for presenting information on additional cannabinoids and terpenes would be helpful to ensure clarity and consistency, as well as compliance with *Natural Health Products Regulations*, for those producers who wish to provide this information. It could, for example, be provided online with information on how to access it provided on the package.

As research on the physiological impacts of additional cannabinoids and terpenes develops, labels should be amended to include information on any that prove to have psychoactive or other properties that may be associated with consumer risk, for example, of impaired motor skills, cognitive impairment or allergic reactions.

Q13: Is there any other labelling information that would help consumers make decisions to support informed and responsible use?

Regulations should require product labelling information that supports safer, informed consumption of cannabis. Research indicates that current labelling requirements do not effectively communicate information on potency, dosage and effects (Leos-Toro et al., 2020; Goodman & Hammond, 2020). Part of the confusion is the result of low levels of consumer product literacy, due to inexperience both with cannabis use in general and with emerging product types in particular.

Communicating THC and CBD levels

The listing of THCA and CBDA, and THC and total THC is confusing and can result in underestimates of product potency. Early evidence suggests interpretive symbols may be more effective in communicating THC level equivalents (Leos-Toro et al., 2020). Additional research is needed on consumer understanding of cannabis product labels and THC and CBD levels.

Information on dose and effects

Developing a standard dose equivalency has the potential to provide significant clarity on dosage and lower-risk consumption. Evidence from research into unit-dose packaging for edibles suggests standard serving information is better understood when products are sold in single-dose servings (Goodman & Hammond, 2020). Packaging in single-dose servings is more easily understandable for young adults than THC amounts (Leos-Toro et al., 2020) and reduces the risk of overconsumption.

COVID-19 measures

Q16: Are there any measures that should be made permanent? What would be the impact if these measures were not continued? Are there any risks of making a measure permanent and how should they be mitigated?

As the pandemic continues, there may be a need to further extend the temporary measures. Any measures put in place to address challenges faced by cannabis licence holders due to the pandemic should be evaluated with regard to impacts on product quality and safety, as well as impacts on production across licence classes, before making these measures permanent.

Additional Considerations

Advertising and promotion

CCSA would like to reiterate that Section 6.1 of the *Cannabis Act* supports health and safety objectives. All prohibitions on advertising and promotion should be maintained. These prohibitions align with research about alcohol and tobacco use that consistently demonstrates that marketing can increase consumption, lower risk perceptions and lead to increased use among young people (Rup, Goodman, & Hammond, 2020). The current approach supports reduced appeal to youth by prohibiting promotion of product flavourings and advertising outside of areas where youth are not permitted by law, aligning with the objectives of the *Cannabis Act*. These limits should be maintained and potentially strengthened to reflect the growing concern around promotional materials reaching youth via social media and other online sources (Rup et al, 2020).

The promotional material consumers are exposed to at point of purchase varies by product and retailer, particularly when purchasing online. There is also considerable promotional information available online through social media. Product descriptions using ambiguous or promotional language to describe product potency and product experience may promote initiation of use (Leos-Toro et al., 2020). Similar to the tobacco industry, where limits have been placed on the ability of producers to induce uptake of a product by reducing claims of harms compared to other products (i.e., describing products as “light,” “extra light,” etc.), promotional materials should not encourage initiation or increased levels of consumption. The question of whether stronger regulatory controls are needed in this area should be addressed through targeted research.

To be effective, the regulations on advertising and promotion require proactive and continued monitoring and enforcement. The proliferation of online information, including social media, poses particular challenges that require additional investments in resources for monitoring.

Conclusion

Amendments to the *Cannabis Regulations* must continue to support public health and safety in line with the intent of the *Cannabis Act*. They should also facilitate increased cannabis-related research, with requirements balanced appropriately to the risks of cannabis use, its status as a legally available product and the need for timely evidence on many questions concerning its use.

As regulations are adjusted to align with consumer needs and literacy, and the promotion of lower-risk cannabis use, ongoing public education will be needed to ensure clear communication of health-related risks and information. To support these goals, there is a need for:

- Clarity in labelling aligned with consumer knowledge and literacy about cannabis compounds;
- Development of a standard dose and its equivalency across product types;
- Targeted research to inform potential regulatory changes to possession limits and labelling requirements; and
- Increased monitoring and enforcement of regulations applying to product promotion, with a focus on online platforms.

References

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