Federal Government Releases its Proposed Approach to Cannabis Regulations

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December 5, 2017

On November 21, 2017, Health Canada released its proposed approach to the regulation of cannabis in anticipation of legalization in July 2018. The proposal addressed seven broad areas relating to cannabis activities: (i) licensing and permitting; (ii) security and security clearances; (iii) cannabis tracking; (iv) cannabis products; (v) packaging and labelling; (vi) cannabis for medical purposes and (vii) health products and cosmetics with cannabis.

Below are some of the notable highlights of the proposed approach to the regulation of cannabis:

Licensing and Permitting

The proposal contemplates different types of authorizations and authorization regimes, which are based on the type of activity being undertaken and, in some cases, the scale of such activity. The authorizations to be granted will allow for the cultivation, processing, sale, analytical testing, import/export and research of cannabis. The license holders will be authorized to conduct the core activity for which the license pertains and supplemental activities. For example, if the license relates to the cultivation of cannabis, the license holder will be permitted to participate in activities such as research and development related to the cultivation of cannabis. Health Canada does not propose to limit the number of licenses that the federal government will be permitted to issue, and has noted that each license will be granted for a term not exceeding five years.

The licensing models for cultivation, processing and sales activities have been broken down into the type of activity being engaged. For instance, the cultivation licenses allow for standard cultivation, micro-cultivation, industrial hemp cultivation and nursery cultivation, the processing licenses will be granted based on whether such activities are deemed as standard processing or micro-processing and the sale licenses will be granted based on whether the sales pertain to medical or non-medical use. Licenses to sell for non-medical use will be limited to jurisdictions where the provincial or territorial governments have not implemented a distribution model. The proposal also contemplates both outdoor and indoor cultivation of cannabis.

In addition to the type of activity, the authorizations granted with respect to cultivation and processing will be based on the scale of such activity. Both the cultivation licenses and the processing licenses allow for "micro" activity, which has been noted as cultivation and processing on a smaller scale. Health Canada is currently considering a number of options to define the threshold of a micro-cultivator and a micro-

processor, and proposes to set this threshold in the final version of the regulations. Holders of these "micro" licenses will be permitted to sell their seeds, plants and harvested materials to other cultivators, processors and holders of research licenses, but will not be permitted to sell directly to the public or to federally-licensed or provincially- or territorially-authorized sellers. The introduction of micro activities is intended to create a market for diverse, craft cultivators and processors and provide opportunities for small and medium sized enterprises within the market.

Products

The proposal indicates that various classes of cannabis would be permitted to be sold under the proposed *Cannabis Act*. Unlike the current Access to Cannabis for Medical Purposes Regulations (the "ACMPR") regime, which only allows cannabis oil to be sold in certain dosage forms and prohibits dosage forms for dried and fresh cannabis, the proposal contemplates additional product forms, including edibles. The purpose of this broadened scope is to displace the illegal cannabis market, however, the final version of the *Cannabis Act* that was passed by the House of Commons on November 27, 2017 indicates that a regulatory framework for edible products is targeted for July, 2019 as opposed to July, 2018.

Labelling and Packaging

The proposal calls for all cannabis products to be packaged in a tamper-evident and child-resistant manner and for product labels to contain specified product information, such as the name of the processor who packaged the products, product lot number, and THC/CBD content. Although the general labelling requirements would be the same for cannabis being sold for medical and non-medical purposes, cannabis sold for medical purposes would also need to include additional client-specific information. Further, labels for cannabis oil products would have to identify the type of carrier oil used and the name of certain allergens.

Similar to the health warning message attached to tobacco products, rotating mandatory health warnings will be required on all cannabis product labels. Further, in order to prevent accidental ingestion of edible cannabis products, the proposal also recommends that a standardized cannabis symbol be affixed on labels for all products intended for ingestion that contain more than 10 parts per million THC.

The proposal recommends that the labelling and packaging of cannabis products involve strict limits on the use of colours, graphics, and font. The proposal calls for the standardized cannabis symbol and health warning messages to be the most prominently displayed elements on product packaging. It is contemplated that regulations may limit the use of colours on packaging and restrict the relative size, colour, and placement of brand elements. The proposed *Cannabis Act* itself prohibits testimonials and lifestyle branding and packaging that is appealing to youth. While these strict requirements were expected given the government's previously stated goal of ensuring cannabis products are not marketed in a manner that appeals to youth, they do not go so far as requiring generic or plain packaging.

Finally, the proposal recommends that the maximum amount of cannabis sold in a single package be 30 grams for dried cannabis and otherwise as outlined in Schedule 3 of the proposed *Cannabis Act*.

Security

The proposal establishes personnel and physical security requirements, which represent a marked reduction from the security obligations currently in force for licensed producers under the ACMPR.

Pursuant to the proposal, the Minister of Health will have the authority to grant, refuse, suspend or cancel a security clearance. An individual will not be eligible to apply for a security clearance if, in the preceding five years, the individual has been refused a security clearance or had their security clearance cancelled. Further, holders of valid security clearances will be required to notify the Minister of Health if they are charged with any offence under the *Criminal Code*, the *Cannabis Act*, the *Controlled Drugs and Substances Act* or the *Food and Drugs Act*. Health Canada anticipates that individuals with histories of non-violent, lower-risk criminal activity may seek to participate in the legal cannabis industry, and is seeking feedback through the public consultation process as to whether such individuals should be granted participation rights.

While the proposal represents less cumbersome security obligations, one area of heightened obligation is the group of individuals required to apply for security clearance. In addition to individuals holding "key positions", the proposal would broaden the applicant group to include directors and officers, shareholders holding more than a 25% interest and any individual in a legal position to bind the license applicant or license holder. Although the number of individuals expected to obtain security clearance has expanded, there are reduced requirements for such individual's presence. The ACMPR currently requires that a "responsible person in charge" or an "alternate person in charge" who holds a valid security clearance be present whenever other employees are present in the room with cannabis. In contrast, the proposal contemplates that at least one individual holding a security clearance be on site during normal business hours. In further contrast to the current ACMPR licensing regime, the proposal allow for portability of security clearances. This portability will eliminate the barrier imposed on individuals looking to transfer employment between licensees as the individual holder will be able to maintain its security clearance so long as the Minister of Health is notified of the change.

In addition the proposal sets forth various standards for physical security requirements. For standard cultivation and standard processing licenses, as well as for federal sale licenses where cannabis is stored on-site (for both medical and non-medical purposes), the proposal suggests that (i) the entire perimeter be visually monitored at all times using a visual recording device and such recordings must be kept for one year, (ii) the perimeter be secured in a manner that prevents unauthorized access, and (iii) an intrusion detection system be operative at all times. Although the security requirements contemplated are similar to those required under the ACMPR, the proposal reduces the requirement to retain copies of the visual recordings for two years under the ACMPR to one year. In addition, the physical security requirements

applicable for micro-cultivation, micro-processing, nursery cultivation and hemp cultivation licenses, as well as in areas where cannabis is not stored, would be significantly reduced such that the requirements for visual monitoring at all times, visual recordings to be kept for one year and maintaining an operating intrusion detection system are not required. If implemented, these revised security measures would provide licensed producers with significant cost savings.

In connection with the proposed regulatory framework, the federal government has launched a public consultation process and has invited all Canadians and interested stakeholders with an opportunity to share their views until January 20, 2018.

Cannabis Tracking

The proposal will enable the Health Minister to establish and maintain a national cannabis tracking system ("CTS") to track cannabis throughout the supply chain. The CTS will serve as an expansion to the current reporting processes used by licensed producers under the ACMPR, and will apply to any person authorized to conduct activities related to cannabis, either through the *Cannabis Act* or through provincial or territorial legislation. The CTS will require reporting of all transactions involving cannabis, with the exception of industrial hemp, on a monthly basis (except in cases of losses and thefts, which require disclosure within 10 days of detection). In combination with the personnel and physical security requirements set out above, the CTS is intended to prevent the diversion of the legal supply of cannabis into an illegal market.

To provide your feedback on Health Canada's proposed approach to the regulation of cannabis, visit: <u>https://www.canada.ca/en/health-canada/programs/consultation-proposed-approach-regulation-cannabis.html</u>.

We Can Help

For more information on how Cassels can assist with your business, please contact Alison Hayman, Jonathan Sherman, Amanda Metallo or another member of our firm's cross-disciplinary Cannabis Group.

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