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Health Canada Releases Consultation Paper on the Regulation of Cannabis – Part 2

In November 2017, Torkin Manes published an article that provided an overview of Health Canada's consultation paper, Proposed Approach to the Regulation of Cannabis (the **"Consultation Paper"**), which sets out proposals regarding the regulation of cannabis in Canada. Specifically, we considered the proposals related to licensing, permits and authorizations and security clearances. This article considers the remaining proposals in the Consultation Paper, namely:

- Cannabis tracking system;
- Cannabis products;
- Packaging and labelling;
- Cannabis for medical purposes; and
- Health products and cosmetics containing cannabis.

Cannabis Tracking System

Under Bill C-45, *An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the "**Cannabis Act**"), the Minister of Health (the **"Minister"**) is authorized to establish a national Cannabis Tracking System (the **"CTS"**) that enables the tracking of cannabis throughout the supply chain. The purpose of the CTS is to provide governmental authorities with data to verify compliance with federal and provincial cannabis laws and to prevent the diversion of cannabis into the illegal market. It is proposed that all persons authorized to conduct activities involving cannabis be required to report into the CTS on a monthly basis through an online portal.

Cannabis Products

Health Canada's proposals in the Consultation Paper enable the sale of a range of cannabis products to the public, specifically permitting the sale of the following classes of products: dried cannabis, cannabis oil, fresh cannabis, cannabis plants, cannabis plant seeds, edibles containing cannabis and cannabis concentrates. The Consultation Paper recommends permitting the sale of all the product classes upon the Cannabis Act coming into force, except for edibles and cannabis concentrates, which would be permitted within one year of the coming into force of the Cannabis Act.

Dosage forms of cannabis products such as pre-rolled cannabis and vaporization cartridges, which are not currently permitted under the *Access to Cannabis for Medical Purposes Regulations* (**"ACMPR"**) regime, would be permitted for sale in the recreational market pursuant to the regulations proposed in the Consultation Paper. What would not be permitted, however, is the mixture of cannabis with prohibited substances listed in Schedule 5 of the Cannabis Act, which include nicotine, caffeine and alcohol.

In line with the purposes of the Cannabis Act, the proposed regulations in the Consultation Paper seek to deter and reduce the appeal of cannabis to youth. As such, the sale of cannabis that has any appearance, shape or other sensory attribute that would reasonably appeal to youth is strictly prohibited.

Packaging and Labelling

The Cannabis Act contains general prohibitions on the promotion, packaging, labelling, and display of cannabis and cannabis accessories. The Cannabis Act prohibits the sale of cannabis and cannabis accessories that are packaged and labelled in a manner that is appealing to youth or includes elements to encourage consumption, such as lifestyle branding elements or testimonials.

The Consultation Paper proposes comprehensive packaging and labelling requirements. Specifically, it calls for tamper-evident and child-resistant packaging for cannabis products, with no single package containing more than 30 grams of dried cannabis, or the equivalent amount of cannabis for other classes of products such as oil and edibles.

Labelling requirements include a product description, name and contact information of the processor, packaging date and THC/CBD content. There will be strict regulations with respect to the use of colour, graphics and font size on packaging, in order to reduce the appeal of products to youth. It is proposed that packages must include mandatory rotating health warnings, in a manner similar to what is currently in place for tobacco products. Health warnings must include messages with regard to health effects, impaired driving, use during pregnancy, risk of combining cannabis with other substances, and impact on mental health. Finally, a standardized cannabis symbol must be displayed on all products that contain more than 10 parts per million of THC.

Cannabis For Medical Purposes

Health Canada's proposals with respect to the regulation of medical cannabis are generally the same as under the ACMPR regime, with several proposed changes. Under the ACMPR, patients that have the support of their medical practitioner can access medical cannabis in one of the three ways: by registering with a federally licensed producer (**"LP"**), by cultivating their own cannabis if they are over 18 years of age or by designating another party to grow cannabis on their behalf.

One proposed change to the ACMPR regime is to enable the transferability of a patient's medical document, which is required by a patient to purchase medical cannabis from a LP. Under the ACMPR, a patient is limited to selecting one LP from which to purchase medical cannabis. The Consultation Paper proposes that a patient would be able to request the return of his or her medical document in order to select a different LP or, in the event of a merger or acquisition between LPs, the medical document could be transferred between LPs with the patient's consent.

Other proposed changes require Health Canada to notify LPs to not fill cannabis orders from health care practitioners who have contravened a rule of conduct or have been found guilty of certain offences. The regulations also propose to expand the grounds on which the Minister may deny an application by a patient to produce medical cannabis privately or arrange to have a designated producer produce it on his or her behalf on the basis of risks to public health or safety.

Health Products and Cosmetics with Cannabis

It is proposed that health products containing cannabis (including prescription and non-prescription drugs, natural health products, veterinary drugs and veterinary health products, and medical devices) be governed by the current framework under the *Food and Drugs Act* (the **"FDA"**). Under the FDA, such products can only be sold to the public once

they have been approved by Health Canada following a scientific review process, which assesses the safety, efficacy and quality of the product. Also considered in the review process is whether there is a need for healthcare practitioner oversight, in which case the product would be available by prescription only.

Natural health products (**"NHPs"**) are also subject to Health Canada's review process. Currently, there are approximately 220 NHPs containing cannabis that are authorized for sale, all of which contain parts of the cannabis plant that are not captured by the legal definition of cannabis in the *Controlled Drugs and Substances Act* (**"CDSA"**) and contain no more than 10 ppm THC. A new pathway to market is proposed for NHPs containing parts of the cannabis plant that will be regulated under the Cannabis Act, however such products would still be subject to a 10 ppm THC limit.

Veterinary drugs, similar to drugs for human use, must be approved by Health Canada prior to being permitted for sale. In terms of veterinary health products (**"VHPs"**), which are products used to promote the health and welfare of animals (such as vitamins and minerals), VHPs that contain parts of the cannabis plant not subject to the legal definition of cannabis in the CDSA and containing no more than 10 ppm THC are currently permitted for sale, provided they comply with Health Canada's requirements. The Consultation Paper does not propose to change this framework.

The Consultation Paper provides that health products containing cannabis would be subject to certain provisions of the Cannabis Act. Manufacturers of health products containing cannabis would need to comply with the licensing requirements under the Cannabis Act. Subject to certain exemptions, health products would be subject to the restrictions on promotion, packaging and labelling under the Cannabis Act. Precautions are being considered for health products that do not require healthcare practitioner oversight (such as non-prescription drugs and NHPs) by controlling the sale of such products behind a pharmacy counter or using the provincially regulated distribution system.

Certain exemptions from the Cannabis Act are proposed for health products containing cannabis. Given that such products would be subject to Health Canada's review process, restrictions on classes of cannabis and package size would not apply to such products. Prescription health products containing cannabis would be exempt from restrictions on access, such as place of sale, because such products have been reviewed by Health Canada and are subject to the oversight of a healthcare practitioner.

Cosmetics containing cannabis-derived ingredients are currently prohibited, with the exception of certain hemp seed derivatives that contain no more than 10 ppm THC. The Consultation Paper recommends that cosmetics containing cannabis-derived ingredients that are currently prohibited would be subject to the provisions of the Cannabis Act, thus making these cosmetics available for sale to the public.

Conclusion

As the proposed regulations in the Consultation Paper are for consultation purposes only, the public and interested stakeholders are invited to provide comments to Health Canada by January 20, 2018 by way of an online questionnaire or written submission. A set of consultation questions can be found in Annex 1 of the Consultation Paper, and more information can be found on the Government of Canada website.

If Torkin Manes LLP can be of assistance to you in providing your comments to Health Canada, please go to cannabis-law.ca and contact any one of our team members.