The Canadian government recently published its proposed excise duty framework for cannabis products and its proposed approach to the regulation of cannabis that will underpin its forthcoming Cannabis Act. The Act is best known for its provisions that will legalize and regulate non-medical cannabis. The consultation papers provide valuable guidance to industry participants on how the Canadian government envisions the new regime. Specific attention is paid to the following key areas: licensing, permits and authorizations; security clearances; cannabis tracking; cannabis products; packaging and labelling; cannabis for medical purposes; and health products and cosmetics containing cannabis. Both proposals are currently in the public consultation stage with comments due on December 7, 2017 and January 18, 2018, respectively.

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The Cannabis Act has passed third reading in the House of Commons and will now advance to the Senate for review. The Act, intended to come into force in July 2018, provides legal access by adults to non-medical cannabis and sets out provisions to control and regulate its use, production, distribution and sale. This Act is in addition to the existing Access to Cannabis for Medical Purposes Regulations (ACMPR) under the Controlled Drugs and Substances Act, which, subject to some coordinating amendments with the Act, will remain in force.
In anticipation of the coming into force of the Act, the Canadian government has published guidance on its proposed excise duty framework for cannabis products and its proposed approach to cannabis regulation. Both are currently in the public consultation stage with comments due on December 7, 2017 and January 18, 2018, respectively.

The guidance from the Canadian government on excise duty and regulation of industry participants provides welcomed insight into how the government envisions the cannabis industry under the new regime. Below we summarize and highlight the more practical implications of the government’s points of emphasis.

**Proposed Excise Duty Framework**

A new excise duty framework on cannabis will be introduced as part of the existing Canada Revenue Agency (CRA) administered legislation that currently applies excise duties on tobacco, wine, and spirits.

**Applicable to all cannabis products**

With limited exemptions, the excise duty will apply to all products available for legal purchase, including fresh and dried cannabis, cannabis oils, and seeds or seedlings for home cultivation, and will be in addition to any other taxes for products, for example GST and HST. The federal government intends to coordinate duty rates with federal-provincial-territorial taxation.

The excise duty will also apply to cannabis for medical purposes unless produced by an individual (or a designated person) for the individual's own medical purposes.

**Payable by federal licensee**

The excise duty will be payable at the time of delivery to the purchaser. The last federal licensee in the supply chain who packaged the cannabis product for final retail sale will be liable to pay the applicable excise duty. Licensees will have monthly reporting obligations.

**Additional licences from CRA will be required**

Health Canada-licensed cultivators and manufacturers of cannabis and cannabis products will be required to obtain a cannabis licence from the CRA for reporting liability purposes, regardless of whether they have excise duty liability. The licences will be for two years and will not be
automatically renewable. A new licence will need to be applied for at least 30 days prior to expiration of an existing licence. Licence requirements include submission of a business plan, proving sufficient financial resources and providing acceptable security to cover one full reporting period, with a minimum of $5,000 and a maximum of $5 million.

**CRA stamp will be required on all products**

Similar to the tobacco stamping program, all cannabis products that will be removed from the premises of a federal licensee to enter into the Canadian market will be required to be packaged for sale at the retail level and have a CRA-issued stamp affixed to the product. As provincial/territorial duty rates may differ the CRA stamp will be specific for a market and product diversion will be subject to penalties.

**Proposed Regulatory Framework under the Cannabis Act**

The regulations more specifically outline licensable activities and provide some clarity as to how the government will deal with product approvals and authorizations. The stated goal is to create an industry that can ultimately replace illegal activity with quality-controlled cannabis and accommodate both large and small players.

**Licensing**

The proposed framework outlines a licensing system that covers a number of cannabis-related activities: cultivation (standard, micro, industrial hemp and nursery); processing (standard and micro); public sale (medical and non-medical); analytical testing; research; and import/export. All licences will be valid for up to five years. Each licence class sets out requirements related to: notice to local authorities; validity period; location; physical security; personnel security; good production practices; and record keeping and reporting.

While the government offers important guidance on the licensing regime, it remains silent on timelines for licence approvals and amendments to licences. This is important to ensure continuity of a business especially in the current environment of collaborations and mergers and acquisitions in this industry.

*Restrictions on public sale:* Public sale includes sales to adults through online, phone, or mail order in provinces and territories that have yet to enact distribution and sale laws. Where
provinces and territories have established frameworks, each jurisdiction will oversee its own regime. Ontario, for example, has announced that it will only permit online sales through its control board.

**Import and export:** Import and export is limited to the import and export of cannabis for medical or scientific purposes, or in respect of industrial hemp.

**Indoor/outdoor cultivation:** All licence classes will permit indoor and outdoor cultivation. Outdoor growing, while limited by climate, is a new development put forward by the government that could significantly reduce costs for producers and enable smaller growers to participate in the market. Storage and processing must be indoors.

**Security:** The government will establish physical security standards to mitigate the risk of cannabis being removed or stolen from a licensed site or being diverted during transportation.

As part of the compliance measures, Health Canada will require licensees to submit copies of standard operating procedures and records relating to age verification and geo-fencing processes.

Personnel security rules will not require the designated "responsible person in charge" or "alternate person in charge" to be present at all times when employees are present in a room with cannabis. Instead of that individual being present at all times, producers will be required to have one individual with security clearance on site during normal business operations.

The number of individuals requiring identification and security clearance will increase. Anyone in a key position (i.e. a responsible person, the security chief, the master grower and the quality assurance person) or in a position to direct or control the licensed organization (i.e. directors and officers of the organization and any parent company, major shareholders and the owner of the cultivation site) will now need to be identified and hold valid security clearance.

The government will seek consultation on whether to allow individuals with histories of non-violent, lower-risk criminal activity (for example, simple possession or small-scale production) to participate in the industry and obtain security clearance.

Security clearances will be portable between licensees. This will enhance mobility of personnel who already obtained security clearance within the industry and will benefit both employers and employees.

**Tracking**

To prevent diversion into the illegal market, a government-administered national online tracking
system will monitor cannabis throughout the supply chain. Any person authorized to conduct activities with cannabis will be required to report into the tracking system. The Minister of Health will have authority to share information with other governmental authorities.

**Products**

The new framework expands on the range of products currently covered under the ACMPR. It will continue to allow cannabis oil capsules, oral sprays and topical cannabis oil while adding a range of product dosage forms for dried and fresh cannabis, including pre-rolled cannabis and vaporization cartridges containing dried cannabis.

At the outset, the proposed regulations will limit cannabis sales to dried cannabis, cannabis oil, fresh cannabis, cannabis plants and cannabis seeds. The aim is to expand the legislation to include edibles and concentrates within a year of the Cannabis Act coming into force. Among the concentrates slated for legalization in 2018 are vaping solutions.

**Packaging and labelling**

The government proposal borrows extensively from tobacco regulations when it comes to packaging and labelling rules for cannabis. Packaging will be required to be tamper-evident and child-resistant, contain prominently displayed health warnings akin to tobacco products and limit the use of colour, graphics and brand elements (including a standard font size for brand elements in line with other information on the package).

Baseline labelling standards will be uniform for both medical and non-medical cannabis products, with additional client-specific information required for cannabis products intended for medical purposes indicating that the individual is authorized to possess prescribed amounts that may differ from legal limits.

**ACMPR still in force**

The existing medical cannabis regulations of the ACMPR remain in place, save for a couple of caveats designed to align the existing legislation with rules for non-medical use, improve patient access and minimize the risk of abuse of the system.

One of the proposed changes to the current legislation introduces the option for patients to request the return or transfer of their medical document from one federally-licensed seller to
another. This will be relevant where a patient cancels a registration or wishes to change its supplier and/or where mergers and acquisitions alter the composition of licensed sellers. It is recommended that sellers develop a consent form that permits them to transfer a patient’s medical documentation and registration between entities.

In addition to the above, the new framework will do away with the 30-day limitation period for multiple orders that would result in more than a 30-day supply.

### Health products and cosmetics with cannabis

**Product authorizations:** The proposed framework maintains Health Canada’s scientific, evidence-based approach to oversight of cannabis health products that are approved with health claims.

With some modifications, the current regulatory framework for human and veterinary product authorizations will apply to cannabis products, including prescription and non-prescription drugs, natural health products, medical device and cosmetic authorizations.

Products with indications requiring practitioner oversight (for example, if a drug has dependence and/or addiction potential), will be added to the Prescription Drug List (PDL). Substances included on the PDL are limited to sale by prescription only.

Products with low levels of THC and CBD that are deemed safe for effective use without practitioner oversight will be permitted for sale without a prescription.

**Natural health products (NHP):** On the coming into force of the Cannabis Act, more products that do not require medical practitioner oversight and do not exceed 10 ppm THC will qualify under the NHP regulatory framework provided they demonstrate safety and efficacy.

### Questions? Contact Us

If you have any questions or require assistance regarding the proposed cannabis legislative and regulatory framework, please feel free to reach out to any one of the following Gowling WLG professionals: Anita Nador, Lewis Retik, Peter Simeon, Jason Saltzman, or Jacques Shore.
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