

# No site, no review: Health Canada announces new cannabis license application requirements

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[Health Canada has announced](#) it now requires a fully built and compliant site as a prerequisite for all licence applications to cultivate or process cannabis for recreational or medical purposes, or to sell cannabis for medical purposes. This change is effective immediately and affects both new applicants and existing applicants.

## What you need to know

- **Level playing field:** This change treats applicants equally, whether they are applying for a licence for recreational or medical purposes. It applies to micro-, standard and nursery cultivation licence applications; micro- and standard processing licence applications; and sale for medical purposes licence applications.
- **Investment barrier:** This change sets a higher investment barrier for new and existing applicants. Previously, applicants could submit their paper application and wait until they received the green light from Health Canada to fund development of a facility.
- **Reason for change:** [Health Canada reports](#) more than 70% of successful applications passing its initial review over the last three years have not proceeded to an operational stage. Health Canada's change seeks to address this issue, reduce application review wait times and the current delay between initial application and entry to the market.
- **Effect on applications:** New applications will not be reviewed until the applicant has a fully completed cultivation, processing or sales site, that complies with all regulatory requirements. Existing applications will not be substantively reviewed until a fully compliant site is ready, but once site evidence package has been submitted, their complete applications will be eligible for priority review and placed in the review queue according to their original application date.

## New upfront commitment

### Fewer partial application reviews

By precluding new applications without a complete facility from entering the queue, the number of partial applications reviewed by Health Canada should decrease. This change is being made in an effort to eliminate instances where applicants submit a paper application, it undergoes review, but the applicant does not promptly proceed to build a

facility. Health Canada suggests it has spent a significant amount of time reviewing applications from parties that are not ready to proceed to market. This practice has increased the time to licensing for applicants that have a facility ready or were ready to complete their facility shortly after their successful initial, paper application.

## Existing applications

Health Canada currently has 700 applications under review. With this change, whether or not an applicant has a facility ready, Health Canada will review the existing applications for high-level issues and provide a status update to applicants. This high-level review will only assess whether the applicant has selected the appropriate class of licence, if the proposed site is appropriate, and if security clearances and municipal approval materials have been filed.

Existing applications will not be eligible for full review until an evidence package for a fully compliant site has been submitted. Once a site is ready, existing applications will receive priority review as they will be placed in the queue based on their original application date, rather than the date the complete application was submitted.

Existing applications that have already received confirmation-of-readiness letters and entered the Cannabis Tracking and Licensing System (CTLS), but which do not have a facility ready, will not be subject to the high-level review. Similarly, older applications submitted under the *Access to Cannabis for Medical Purposes Regulations* (ACMPR) that received a confirmation-of-readiness letter but have not entered the CTLS and do not have a facility ready, will not be subject to high level review.

## New applications

For new applications, the site evidence package must be received by Health Canada within 10 business days of the applicant's CTLS application submission. Following receipt of the application and site evidence package, Health Canada will screen the application for completeness within a 30-day service standard. Complete applications will then be added to the queue for an in-depth application and security clearance review.

This applies to micro, standard and nursery cultivation licence applications, micro and standard processing licence applications, and sale for medical purposes licence applications.

The security clearance process will not be initiated until the site evidence package is received by Health Canada. With fewer applicants being ready to instigate the security clearance process, processing times for security clearance will improve.

## Reason for change

Health Canada suggests this change is also motivated by a desire to align the cannabis licensing framework with the approach taken in the pharmaceutical sector and other regulated industries. As the cannabis market matures, its framework may converge with other regulatory regimes as Health Canada's view on the appropriate way to regulate a product used both recreationally and for medicinal purposes continues to evolve.

Interestingly, the cannabidiol (CBD) industry is lobbying for change on how these products are regulated and is seeking the removal of CBD from the prescription drug list and proposing it be reclassified as a natural health product (NHP). As an NHP, CBD would be regulated under the *Natural Health Product Regulations* and sold alongside vitamins and supplements in pharmacies as opposed to cannabis retail stores.

## What's Next?

A revised version of Health Canada's Cannabis Licensing Guide reflecting these changes is expected to be available online soon, along with a new Physical Security Measures Guide for Cannabis.

We expect that the regulation of cannabis and cannabis derived products will be in flux for the coming years as Health Canada gains more experience in its regulation of the complex space.

*To discuss these issues, please contact the author(s).*

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