

As many of you are already aware, Health Canada has made significant changes to the application process for all standard and micro cultivation and processing licenses, as well as Sales for Medical Purposes (with Possession of Cannabis).

For anyone not yet aware of those changes, the link below will take you to the Health Canada press release. I would encourage you to read it in its entirety.

<https://www.newswire.ca/news-releases/statement-from-health-canada-on-changes-to-cannabis-licensing-837732427.html>

There are implications for many current applicants. Those implications are dependant on which stage of the application process your file has progressed to. To provide the most accurate and impactful guidance we can, we've identified those stages below. Each section contains our analysis and recommendations for moving forward.

New Applicants:

- Health Canada will no longer process paper-based applications without a fully built facility.
- The Confirmation of Readiness letter (CoR), which previously provided applicants with “approval in concept” will no longer be offered. We recognize that the CoR was a useful tool for investors to feel confident that a given project is viable for licensing.
- Without the benefit of the CoR letter, it will be especially critical to ensure that your facility is built with input and guidance from experienced advisors. In the past, incorporating feedback and changes suggested by Health Canada Reviewers amounted to changes to floorplans, etc. Under this new system, changes flowing from the application review process will be much more problematic as the facility will already be built. There is a definite need to get things right the first time.
- Our initial service offering will shift away from the production of application documents toward supporting the construction of compliant facilities.
- We will prioritize detailed, security-focused floor plan reviews as well as detailed electronic security system design, specification, sourcing, and project management based on our experience (300+ security system designs, 100+ facility build-outs).
- Health Canada will no longer advise new applicants on the viability of their site. Identifying sensitive proximate uses and other factors will be critical. Our experience in this area is significant and we look forward to providing that assistance.
- We have developed some innovative licensing and security strategies for facility build out, applications and evidence packages that we would be pleased to share. Please feel free to contact us.

Pending Applications Without Confirmation of Readiness (CoR):

- You should not expect to receive a CoR or a detailed review of your application submission.
- Health Canada has committed, by the end of June 2019, to completing a preliminary and high-level review of each application in queue. The scope of that review will include; (a) confirmation



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the correct licence classes have been specified; (b) site appropriateness; (c) Initial personnel checks (for security-cleared roles); and (d) notices to local authorities.

- If the application passes this review, the Department will provide a status update letter to the applicant, indicating that, based on a preliminary and high-level review, it has no critical concerns with what is proposed in the application.
- Health Canada has said, “This letter is not, and should not be viewed as an indication that the application is fully compliant, or that a licence will be issued”.
- Health Canada has not clearly outlined what, if anything, they will provide to applicants if the file is judged to be incomplete. We would expect some type of dialogue between Health Canada and the applicant. We can provide support to applicants on site suitability and security clearance checks.
- Once the applicant has a completed site that meets the regulatory requirements, the Department will review the application in detail and on a priority basis in line with the original application date. This will require the submission of application materials/documents as well as a site evidence package. These materials must be prepared/updated and submitted to get an application number and qualify for a licence.
- After submission, Health Canada will begin the detailed review of the materials submitted and provide any feedback/questions they may have. As stated above, changes at this point in the process will be difficult to implement and proven strategies will be critical.

Pending Applications with CoR:

- Health Canada has completed their paper-based review of your application and you should not expect to receive the Application Status Update Letter.
- You are unlikely to receive any further communication from Health Canada on your file until you submit the Evidence of Readiness package showing that you have built a fully built, compliant facility.
- The ability to expand a licensed facility through amendment will remain in place. In order to move your application forward, you may wish to consider a phased approach beginning with a small portion of the facility. There are specific requirements to make this phased approach viable for licensing. Having completed dozens of files using this strategy we would be pleased to provide guidance.
- Those of you who have a CoR issued under the ACMPR, who have not transitioned to the CTLS, must choose whether to pursue that transition. Health Canada has stated clearly that applications attached to finished facilities will be reviewed and processed in chronological order according to the date of the initial submission. In order to maintain your place in the application queue, a transition to the CTLS is necessary. If you choose not to complete the CTLS transition, your submission following the completion of your facility will be reviewed after those applicants who maintained their position in queue. Considering that this change was intended to reduce the strain on Health Canada’s resources, processing times are likely to decrease significantly. The decision to expend the time and resources necessary to complete the CTLS transition will

depend on your perception of the value attached to your place in the queue. We would be pleased to advise further on this point of application strategy.

Applicants Currently Building Facilities

- This change is very positive for applicants in this category. Processing times are likely to decrease significantly, and Health Canada will prioritize your application.
- With less strain on their resources, Health Canada will have the opportunity to complete much more comprehensive and detailed reviews of the applications they receive. Applicants should expect more detailed requests for information. We will be pleased to support you as you address Health Canada's feedback.
- Health Canada's inquiries and feedback will shift from theoretical to practical. Answering requests for information will require much more demonstration as opposed to description, as it was in the past. Application documents will need more accurate and technical descriptions of equipment and processes to meet this new standard. This is another area we look forward to supporting.

General Implications and Analysis

- This change will immediately alleviate the bottleneck within the Security Clearance section as many Security Clearances will be put on hold until facilities are fully built-out. As in the past, Health Canada will not process security clearances until the application is in enhanced review. As we now know, enhanced review will begin after the submission of the full application and evidence of readiness package. Without the current volume of clearances, we expect this process to take significantly less time.
- Given that security clearances will not begin processing until the final submission is under review, it is especially critical that applicants are selective about whom to submit. Problems with the clearance process are likely to remain the biggest cause of delays. The change to application processing format will increase the impact of those delays.
- After many years of assisting clients apply for security clearances, we know the specific challenges that create delays in the clearance process. Applicants need reassurance that the individuals they select for key positions have the greatest possible chance of successfully completing the security clearance process. We offer a variety of pre-screening and background investigative services to identify and avoid potential delays in security clearance.
- The previous application review process contained application milestones which were useful for re-assuring investors and shareholders that the application and business strategy were sound. The new approach does not contain a mechanism for gaining that assurance directly from Health Canada. The only reasonable substitute for that assurance will now come from experienced service providers such as 3 |Sixty Secure. We look forward to providing this level of support to our clients based on 6 years of cannabis licensing and security experience.

In closing, we recognize that for some of you this is not a positive change. You may be forced to re-evaluate your plans moving forward and this is unfortunate. Before determining how to move forward



with your application, we would encourage you to reach out to us for a discussion on available strategies. There are a number of ways to ensure that your application remains viable and we would be pleased to advise and assist.

At 3|Sixty Secure, our core focus is seed-to-sale security and license application strategy. We have more direct experience managing the security aspects of facility build-outs than any other service provider in the Canadian cannabis market. We look forward to leveraging our knowledge and experience to support you as you move towards licensing.