There are seven stages to the application process for becoming a licensed producer of marijuana for medical purposes:

- 1. Applications received
- 2. Preliminary screening
- 3. Enhanced screening
- 4. Initiation of security clearance process
- 5. Review
- 6. Pre-licence inspection
- 7. Licensing

# **Preliminary Screening**

When an application is received, it undergoes a preliminary screening for completeness. If an application is not complete, it will be returned. If an application appears to be complete, it will be assigned an application number. The application number means that the application has completed the preliminary screening. Applicants should reference their application number in all correspondence with Health Canada.

### **Enhanced Screening**

Once an application has been assigned an application number, it will be reviewed to ensure: that the location of the proposed site does not pose a risk to public health, safety and security; that the proposed security measures outlined in the application meet the requirements of the MMPR; and the proposed quality assurance person has the appropriate credentials to meet the good production requirements outlined in Division 4 of the MMPR. On a case-by-case basis Health Canada may also request and/or review other information that is relevant to the application.

Health Canada will also verify that applicants have provided notice (required by section 38 of the MMPR) to the senior official with the local government where their proposed site is located.

Applicants are required to comply with all applicable provincial/territorial and municipal laws, including zoning restrictions, fire and electrical safety, and waste management.

# **Security Clearance**

Once the screening of an application is complete, the security clearance forms for key personnel will be sent for processing.

When applying for a licence to produce under the MMPR, a Security Clearance Application form must be submitted by the following individuals:

- the proposed senior person in charge;
- the proposed responsible person in charge;
- the proposed alternate responsible person(s) in charge (if applicable);

- if a producer's licence is issued to an individual, that individual; and,
- if a producer's licence is issued to a corporation, each officer and director of the corporation.

The requirement for these individuals to have a valid security clearance is outlined in section 24 of the MMPR.

For more information on the security screening process please visit <u>Security Clearance Process</u> web page.

#### **Review**

An application will be thoroughly reviewed to validate the information provided. Given the extensive review process, applicants should anticipate communicating with the Office of Controlled Substances multiple times to provide clarifications on the application. Health Canada may also request additional information from the applicant as required.

Physical security plans will be reviewed and assessed in detail at this stage. Please note that applicants must meet a minimum of a level 7 (as defined in the Directive on Physical Security Requirements for Controlled Substances (Licensed Dealers Security Requirements for the Storage Of Controlled Substances) to be considered for a licence. Physical security must comply with the Directive.

When Health Canada believes an application is ready for a pre-licence inspection, Health Canada will contact the applicant and identify the information that needs to be confirmed before a pre-licence inspection can be scheduled. This includes, but may not be limited to confirming how the applicant has indicated in their application that they would comply with Division 3 (Security Measures) of the MMPR.

### **Pre-licence inspection**

Section 9 of the MMPR (Inspection of Site) allows for the possibility of a pre-licence inspection. This includes, but is not limited to: Security Measures, Good Production Practices, Packaging, Labelling and Shipping, Registration, and Record Keeping. For information on preparing for inspections, please reference Inspections - What to Expect. <a href="http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/licencedproducer-producteurautorise/inspections-eng.php">http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/licencedproducer-producteurautorise/inspections-eng.php</a>

### Licensing

The results of the pre-licence inspection are reviewed in conjunction with all the information submitted to Health Canada, and any other relevant information, to complete the assessment of the application in keeping with the requirements of the MMPR, establish that the issuance of the licence is not likely to create risks to public health, safety or security, including the risk of cannabis being diverted to an illicit market or use, and there are no other grounds for refusing the application.

The process for the initial issuance of a licence includes limits on licensed activities and a maximum limit on the total amount of marijuana authorized for production. For more information on the issuance of licences, please see the information bulletin on the Issuance of Licences to Produce Marijuana for Medical Purposes. <a href="http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/licencedproducer-producteurautorise/licences-eng.php">http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/licencedproducer-producteurautorise/licences-eng.php</a>

# **Changes to Applications**

Any changes to your application (e.g. changes in key personnel, physical security measures) may result in additional processing time. If you wish to change your proposed site, you may be required to withdraw your application and resubmit your application based on the new site.

# **Considerations for Applicants**

Application processing times are variable and depend on a number of factors, including:

- the completeness of the application and the thoroughness of the information provided;
- the timeliness of applicant responses to requests for additional information;
- the readiness of the applicant to move through the process;
- the complexity of the application; and,
- whether the application poses any risks, including a risk to public health, safety or security.

The timeline for security screening of key personnel can also vary depending on the complexity of the applicant's file.

The entire application process can take more than a year to complete.

It is the responsibility of the applicant to ensure that the information provided in their application is detailed and accurate and clearly demonstrates that they are compliant with all the requirements of the MMPR. Insufficient or inaccurate information may give rise to a grounds for refusal.