MEDICINAL CANNABIS AGENCY

MANATŪ HAUORA
MINISTRY OF HEALTH

GUIDELINE ON THE REGULATION OF MEDICINAL CANNABIS IN NEW ZEALAND

Part 4

Guidance for applicants for a medicinal cannabis licence

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Contents

Section 1: Introduction

This document is the *Guideline on the regulation of medicinal cannabis in New Zealand - Guidance for applicants for a medicinal cannabis licence*. It aims to help you to apply for a medicinal cannabis licence under the Misuse of Drugs Act 1975 (the Act) and the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations).

We recommend you read all *Guidelines on the regulation of medicinal cannabis in New Zealand* in full, these can be found on our website at: https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms.

While we have made every effort to explain the information that you need to provide in your application, it is your responsibility to understand your obligations under the Act and the Regulations and provide true and accurate information in your application.

Please send all correspondence about your application to medicinalcannabis@health.govt.nz.

1.1 Before submitting an application

When applying for a medicinal cannabis licence, please ensure that you allow sufficient time for the Agency to process and assess your licence application.

This is particularly important where the activity you wish to undertake is seasonal or cyclical (eg, outdoor cultivation).

To avoid any unnecessary delays, please ensure that the application is complete, accurate and provides all required information in a clear and succinct manner.

The Agency aims to process applications within 60 working days. However, it should be noted that this time does not include time taken by applicants to respond to requests for information, or where there are delays in criminal convictions checks, which are outside the control of the Agency.

1.2 Medicinal cannabis licencing framework

The Regulations provide for a single medicinal cannabis licence that authorises the licence holder to carry out one or more of the following types of licensed activity:

- cultivation
- seed supply
- research
- possession for manufacture
- supply.

A single application can be submitted to conduct the activity or combination of activities you wish to be licensed for, at one or more locations.

You must apply for at least one activity in your initial application for a medicinal cannabis licence. Licences can be amended to add additional activities to an existing licence. (See section 6 for information on the application process and associated fees for amendment of a licence.)

The assessment of your application includes consideration of factors such as the suitability and security of your location, and the proposed processes and practices in place to conduct the activities you wish to undertake. In addition, the eligibility of the applicant and responsible persons involved in the application to hold a medicinal cannabis licence is also assessed.

Licences are only able to be issued where the applicant can demonstrate that all applicable regulatory requirements are met.

For more information on the licensing framework, see the *Guideline on the regulation of medicinal cannabis in New Zealand - Overview of the medicinal cannabis licensing scheme* available on our website at: https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms.

1.3 Fees

Applications for medicinal cannabis licences include both an initial check fee and once accepted for assessment, an application fee.

The Agency is unable to begin assessment of an application until the relevant fee is paid, and it is important to note that the fees are application fees (ie, the fee is not refunded if your application is unsuccessful).

Invoices will be issued to you at the time payment for an initial check or application fee is required. Please do not make payments prior to receiving the invoice.

Information on both the fees associated with new medicinal cannabis licence applications and the fees associated with the renewal of existing licences, are included below.

For information on fees for amendments to an existing medicinal cannabis licence please refer section 6.2.2.

1.3.1 Initial check

Fee for initial check of application: $345 (including GST).

On receipt of your application, an invoice will be issued to you for the initial check. The initial check involves ensuring that you have completed your application in full and that it is ready for assessment.

The fee for the initial check is charged for each application, no matter how many activities you are applying for. This fee also applies if you are applying to renew your licence.

Please be aware that once an application is submitted and you have paid the initial check fee, should you decide to withdraw your application the initial check fee is non-refundable.

1.3.2 Application and renewal fees

Medicinal cannabis licence application fee: $2,587.50 (including GST).

Renewal fee (each year): $2,587.50 (including GST).

Where an application for a new medicinal cannabis licence or renewal of an existing medicinal cannabis licence is accepted for assessment, the medicinal cannabis licence application fee is required to be paid.

Please note an application fee is not required for the amendment of a licence (see section 6.2.2).

1.3.3 Activity fees

In addition to the licence application fee, a fee is payable for each activity or location to be authorised under your medicinal cannabis licence. The table below outlines the fees for each activity.

Notes:

- The fee for the supply activity does not include the fee for assessing a product against the minimum quality standard. See the *Guideline on the regulation of medicinal cannabis in New Zealand - Overview of the medicinal cannabis licensing scheme*.
- The medicinal cannabis licence application fee does not include the fees associated with other licences that may be required, such as a licence to manufacture medicines under the Medicines Act 1981 or a licence to export controlled drugs. See the *Guideline on the regulation of medicinal cannabis in New Zealand - Overview of the medicinal cannabis licensing scheme*.

Activity fees under a medicinal cannabis licence

Activity	Activity fee per location (including GST)
Cultivation	$5,462.50 new $3,392.50 renewal
Seed supply	$747.50 new $747.50 renewal
Research (clinical trials only)	No fee
Possession for manufacture	$3,105 new $2,645 renewal
Supply	$6,382.50 new $5,922.50 renewal

1.3.4 Examples of how to calculate application fees

New medicinal cannabis licence

In this example, an applicant wishes to apply for a new licence that authorises cultivation and supply activities. The cultivation activity will take place at two separate locations, while the supply activity

will take place at a third location. The initial check of the application confirms that the applicant has provided all necessary information and documents.

The total fees payable are $20,240 (including GST), comprised of:

- $345.00 for the initial check of the application
- $2,587.50 licence application fee for consideration of the medicinal cannabis licence
- $10,925.00 for consideration of two locations for cultivation activity ($5,462.50 for each location)
- $6,382.50 for consideration of the supply activity (one location only).

Renewal of an existing medicinal cannabis licence

In this example, an applicant wishes to renew a licence that authorises possession for manufacture and supply activities. The possession for manufacture and supply will both take place at the same location. The initial check of the application confirms that the applicant has provided all necessary information and documents.

The total fees payable are (including GST), comprised of:

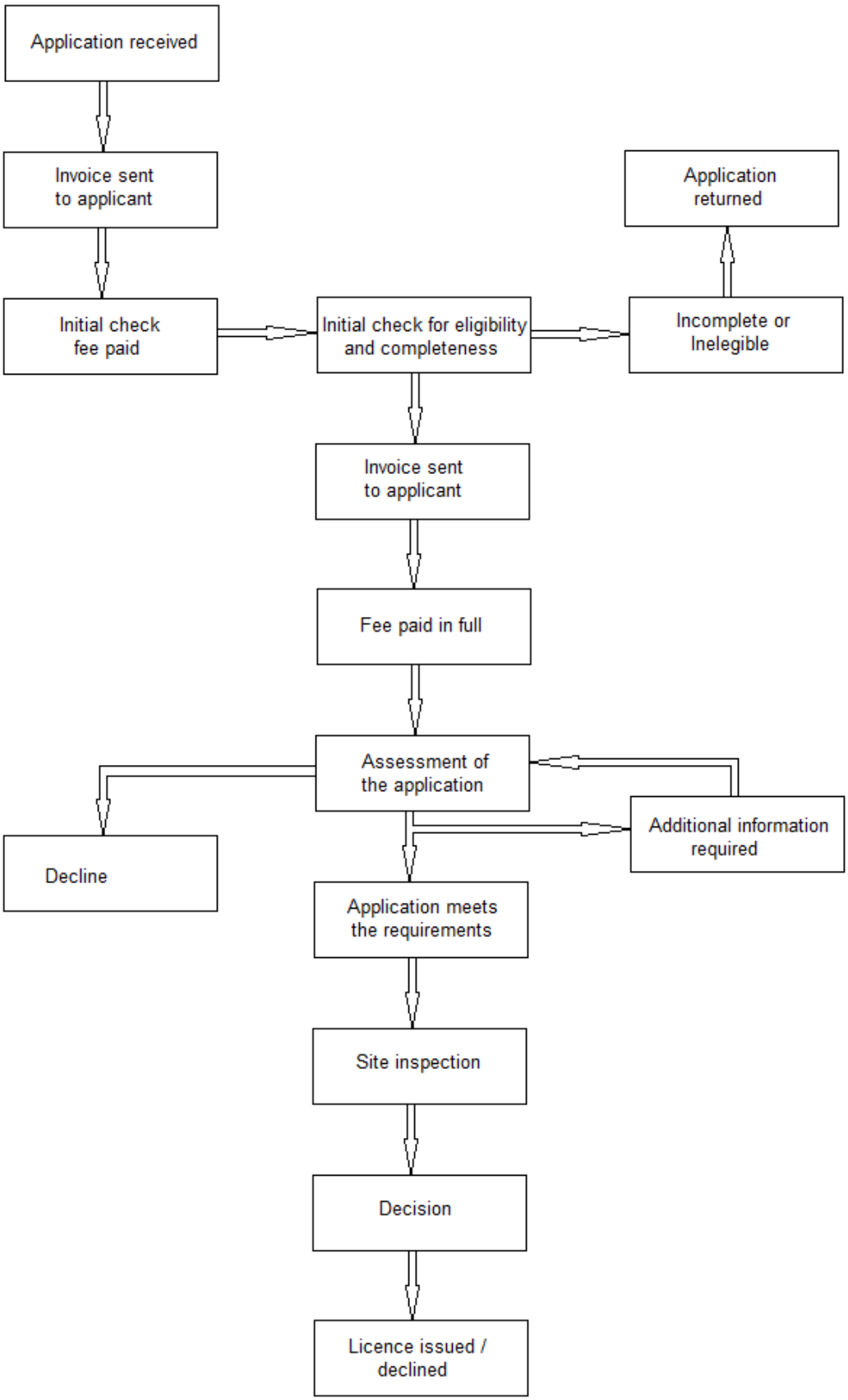
- $345.00 for the initial check of the application
- $2,587.50 licence application fee for consideration of the medicinal cannabis licence
- $2,645.00 for consideration of the possession for manufacture activity
- $5,922.50 for consideration of the supply activity.

Note that two invoices will be issued (one for the initial check on receipt of the application and the remainder issued once the application is accepted for assessment).

1.4 Licensing process

The licensing process is summarised in the following section. The process is shown in a flow chart, and the four major steps are described in detail.

1.4.1 Summary of the licensing process



Step 1: Initial check of application

When we receive your application, we will invoice you for the initial check of your application. Once payment of the invoice has been received, the initial check will be conducted.

The purpose of the initial check is to ensure you have completed your application and have included all the relevant documents. At this stage, we may ask you to provide additional information or to make minor adjustments to your application so that we can complete the initial check.

If the initial check finds your application is not in order, we will return the application and advise you that you will need to submit a new application. If the application is returned and you decide to submit a new application, this will incur a new initial check fee.

If the initial check verifies that the application appears to be in order, then we will calculate the application fee and invoice you for the full assessment of the application.

Step 2: Full assessment of application

Once payment of the full assessment fee has been received, assessment of your application can begin.

While assessing your application, we may request additional information or clarification of the information provided. Your application will not be progressed until you provide the requested information or clarification.

Minor changes to an application such as correction of a phone number or misspelt address details, are usually able to be accommodated. However, significant changes that may affect the outcome of the application or require reassessment, such as changes to responsible persons or location information, may require submission of a new application and payment of further fees. Should this be the case, please contact the Agency to discuss.

Step 3: Inspecting the location

Once we have assessed your application and are satisfied that on the basis of the information you have provided in your application, that a licence could potentially be issued, an inspection of each site at which an activity is to be undertaken will be required.

You will be notified at the point in the process where you can request an inspection of the sites to be licensed.

You should not arrange for an inspection until:

- all construction at your facility has been completed
- the security measures have been installed
- the security procedures have been put in place.

Please note, that whilst the Agency makes every effort to accommodate requests for inspections as soon as reasonably possible, you should allow a minimum period of one month between contacting the inspector and the date the inspection is conducted.

The Agency will not issue a licence until each location has been inspected and you have addressed all issues identified during the inspection.

Step 4: Issuing a Medicinal Cannabis Licence

If we consider that your application meets the regulatory requirements, the Agency will issue a licence for you to carry out the relevant activities at the specified location or locations.

The Agency issues a medicinal cannabis licence for a period of one year. Licences can be renewed on a yearly basis.

1.4.2 If your application is declined

In the case where your application is declined, you will be notified of this.

If the Agency declines your licence application, you may apply to the Director-General of Health for a review of the decision. Any application for a review must be received by no later than 14 days after the day we provided you with the notice of the decision.

Section 2: Overview of the medicinal cannabis licence application form

In order to apply for a medicinal cannabis licence you must complete an application form. For a new medicinal cannabis licence you must complete Form A and to renew a medicinal cannabis licence you must complete Form R. Both application forms require you to provide information on:

- the applicant – giving details for an individual or an entity (body corporate or partnership); and
- the types of activities to be covered by the licence.

Information on the structure of an application form, and guidance on each section which you are required to complete is found below.

Application forms can be found on our website at https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms.

Note that the application form identifies the minimum information the Regulations require. You should provide as much additional information as necessary to describe your proposed activities.

To submit your completed application, please email the application form and all supporting documentation to medicinalcannabis@health.govt.nz.

Should you wish to submit your form in hardcopy these may be posted to:

Medicinal Cannabis Agency
Ministry of Health
PO Box 5013
Wellington 6145

2.1 Structure of the medicinal cannabis licence application form

The application form (Form A or Form R) for a medicinal cannabis licence contains six sections.

- Section A: Applicant details and declaration
- Section B: Cultivation activity
- Section C: Seed supply activity
- Section D: Research activity
- Section E: Possession for manufacture activity
- Section F: Supply activity.

All applicants must complete section A, and the sections relevant to the activities to be licensed.

Complete an additional copy of each activity section for each additional location where you are planning to conduct the activity. For example, complete two Section B forms if you intend to cultivate cannabis at two different locations.

2.2 Section A – Applicant details and declaration

This section:

- requests information on the applicant (whether an individual or entity) and any responsible persons
- seeks the applicant's authorisation to carry out Ministry of Justice criminal conviction checks on these persons.

2.2.1 Eligibility to hold a licence

All applicants, whether an individual or a director or partner in an entity must be 18 years of age or older.

For an individual applicant they must reside in New Zealand.

In the case of an entity:

- Where the applicant is a body corporate, it must be incorporated in New Zealand.
- At least one director of the body corporate must reside in New Zealand.
- For partnerships, all the partners must reside in New Zealand.

All individual applicants, and one or more directors or partners of the entity must have the expertise, and the individual or entity must have the resources, to comply with the obligations the Regulations place on the licence holder for the types of licensed activity they are seeking a licence for.

Individual applicants and in the case of an entity, directors and partners, must not have:

- had a licence issued under the Misuse of Drugs Act 1975 or any regulation made under that Act that has been revoked
- had a conviction under the Misuse of Drugs Act 1975 or any other drug-related offence.

And in the case of an entity, directors and partners, must not have:

- been convicted of a crime involving dishonesty within the meaning of the Crimes Act 1961
- been convicted of an offence overseas that, if committed in New Zealand, would be an offence under the above legislation.

Should an applicant have had a licence revoked or a conviction as listed above but wish to be considered for eligibility to hold a licence, it may still be possible, but further consideration and approval is required. Please note that this is likely to add additional time to the application process.

Convictions covered under the Criminal Records (Clean Slate) Act 2004 may not need to be disclosed. For more information, please visit the Ministry of Justice website (https://www.justice.govt.nz/criminal-records/clean-slate/) or seek independent legal advice.

2.2.2 Applicant details

All applications must have a contact person who the Agency will communicate with on all matters to do with the licence application. In the case of an individual applicant, the applicant will be the

contact person. In the case of an entity, the nominated person should have the authority and ability to answer questions about the application.

2.3 Eligibility to be a responsible person

If the licence applicant is an individual, that individual will be regarded as the responsible person for the purposes of the application and the licence (if issued).

If the licence applicant is an entity, the Regulations require the entity to nominate one or more individuals to be a responsible person who is familiar with and has the expertise to comply with the obligations the Regulations impose. The entity may nominate different people as the responsible person for each activity and/or location.

The nominated responsible persons must be authorised by the entity, to control the activity or activities they are seeking a licence for, and to communicate with the Agency on behalf of the entity.

A responsible person must be 18 years or older and live in New Zealand.

A responsible person must not have:

- had a licence issued under the Misuse of Drugs Act 1975 or any regulation made under that Act that has been revoked
- had a conviction under the Misuse of Drugs Act 1975 or any other drug-related offence
- been convicted of a crime involving dishonesty within the meaning of the Crimes Act 1961
- been convicted of an offence overseas that, if committed in New Zealand, would be an offence under the above legislation.

Should an applicant have had a licence revoked or a conviction as listed above but wish to be considered to be authorised as a responsible person on a licence, it may still be possible, but further consideration and approval is required. Please note that this likely will additional time to the application process.

Convictions covered under the Criminal Records (Clean Slate) Act 2004 may not need to be disclosed. For more information, please visit the Ministry of Justice website (https://www.justice.govt.nz/criminal-records/clean-slate/) or seek independent legal advice.

Every responsible person nominated on the application must complete 'Section A5: Responsible person details and declaration'.

2.4 Request for criminal conviction history

The Regulations require the Agency to check with the Ministry of Justice whether an individual applicant, director, partner or nominated responsible person has any convictions for relevant crimes or offences.

The Agency will request the Ministry of Justice to conduct a check when it has accepted the application for full assessment.

For the Agency to submit a request, you must provide an email address in the application form for all directors, partners and responsible persons, and provide copies of the required identification documents.

Each person for whom a check is required, must submit a copy of an identification document to the Agency. The identification document must:

- be a clear and readable copy
- exactly match the details in your form – write your name on the form exactly as it is on your identification document
- not be defaced
- clearly show the expiration date (this is on the reverse side of some driver licences).

The identification document must be one of the following:

- a New Zealand driver licence. This can be current or expired within the last two years but must not be cancelled or a temporary licence.
- a New Zealand passport. This must be signed and can be current or expired within the last two years but must not be cancelled.
- an overseas passport. This must be signed and current.
- a New Zealand firearms licence. This must be current.

If the person does not have one of these forms of identification, that person must complete a proof of identification form and make a statutory declaration and submit these to the Agency.

The completed form can be signed by hand or using an electronic signature. The signature on the form must match that of the signature on the identification document. Typed signatures are not accepted.

Once your application is submitted to the Agency, each person requiring a criminal conviction history check will receive a link to an online application form directly from the Ministry of Justice. The recipient must complete the online form within 15 days of receiving the link to give authority to release the details of any criminal convictions.

Please note that as this check involves an external process, the Agency does not have control over how long it will take to receive the results. The Ministry of Justice advises that it aims to process all requests within 20 working days.

2.5 Statutory declaration

To complete this section of the application, the applicant is required to complete a statutory declaration.

In order to sign the declaration, this can be physically signed if completing the form in hardcopy, or may be completed electronically, if you have an electronic signature facility such as a Digital ID file.

Section 3: Completing the application form for a medicinal cannabis activity

You must apply for the medicinal cannabis activities you wish to conduct on the relevant section (B–F) of the application form. Each section of the form covers a particular activity and requires information on:

- the location of the activity
- the security arrangements for the specified location
- specific details about the activity.

This section provides general guidance on completing these sections.

For more details on the activities for which the Agency can issue a medicinal cannabis licence, see the *Guideline on the regulation of medicinal cannabis in New Zealand - Overview of the medicinal cannabis licensing scheme*.

For specific guidance on completing the application for an individual activity, see Section 4.

3.1 The location or locations for each activity

A medicinal cannabis licence authorises an activity at a specific location. If you intend to conduct a licensed activity at more than one location, you must submit a separate activity application section for each location where you will carry out the activity.

For each location, you must provide:

- its physical address (the street address)
- its legal description and the area of the land and premises
- its geographical coordinates
- a plan or map, if required to identify the location.

Include a geographical plan of the location showing those areas where you propose to grow, manufacture, test or store the cannabis and cannabis products. For outdoor cultivation locations, provide a full description of the geography of the cultivation area, including any natural features, structures (for example, fence lines, buildings, or sheds), roads and paths present.

For buildings, include details of the nature of the construction of the facilities, access points such as windows and doors, and restricted areas of access. Also include floor plans and photographs of the buildings and facilities (if relevant).

In your location descriptions, you should clearly identify the specific buildings (and the rooms within these buildings) or outdoor areas where you will carry out the activity. If you gain a licence for the activity, the licence will authorise that activity to happen only at the location you have identified in your application.

3.1.1 Being entitled to use the location

As the applicant, you must be entitled to use the location or locations that you specify in the application for the activity or activities you are seeking a licence for. This means that you will either own the property or have written permission from the owner to use the property for the activity or activities you are seeking a licence for. Where an agreement is provided (such as a lease) it must clearly include permission from the owner for medicinal cannabis activities to be conducted at the location. Being entitled to use the location also means that you acknowledge that you meet local by-laws and permissions to conduct medicinal cannabis activities at the location. For more information on this, contact your local authority or council.

3.2 Security arrangements at the location

In your application, you must include details of the security arrangements in place to minimise the risk of cannabis and cannabis products being diverted to illicit use. The Agency will take a risk-proportionate approach to decide whether your security arrangements are adequate for the activities you wish to undertake. Factors we will consider include, but are not limited to:

- delta-9-tetrahydrocannabinol (THC) levels of the plants you plan to cultivate
- the nature and size of the operation
- the types of cannabis products you plan to produce
- the amount of cannabis or cannabis products you plan to store
- the nature of the physical location (for example, a cultivation location next to or nearby to residences, schools, or areas with significant public access past the site would not be appropriate)
- physical security, security of operational procedures and personnel security arrangements.

You should have a security plan that describes in detail your arrangements for physical measures and operational procedures relating to security at the location.

- Physical measures should cover the physical barriers to limit intrusion and systems to enable detection (eg, surveillance) and raise alarms.
- Operational procedures relating to security should include processes to check the facility for attempts at unauthorised access, that staff and visitors are authorised to be in the location, and to minimise theft or misappropriation. See Section 5 for more information on Standard Operating Procedures.

You should also have procedures to ensure that staff working with cannabis and cannabis products are appropriately trained in the security requirements.

As part of the assessment of your application, the Agency considers the security arrangements provided in your application form (and accompanying documents) and when satisfied that the arrangements could be potentially licensed, verifies the information provided through the onsite inspection of each location.

Once verified, your security arrangements will form part of your licence obligations. We may continue to review those arrangements through the ongoing inspection and compliance framework.

Appendix 1 contains tools to help you to develop a security plan. Please be aware that the provided tools are intended as a guide only and may or may not be applicable for your particular situation. You may find it useful to engage with a security specialist to conduct a security assessment of the location and operations to identify appropriate security arrangements.

3.3 Tracking and record keeping

As a licence holder, you must keep records of the amounts of cannabis (in the form of seed, plant, starting material, cannabis-based ingredient, or product) that you:

- cultivate
- maintain for the purpose of propagation
- produce, possess and store
- supply under the licence
- receive from another licence holder
- hold and administer under a licence with a research activity
- destroy or dispose of.

You must also keep records of:

- any failure to sow cannabis seeds intended for sowing
- the failure of any cannabis seeds to germinate, or of any crop to reach maturity.

In your application, you must (where applicable) provide details of the record-keeping arrangements you have in place to track and trace the life cycle of each of the cannabis plants grown. This may be from seed or cutting, through to harvest, drying and processing, through extraction or manufacture, and through supply or administration. Those arrangements should include accounting for destruction or disposal of any plant material or product.

Records may be kept electronically or in hard copy (ie, paper). The system used must be secure and unable to be amended or tampered with. For example, a Word document or Excel spreadsheet is not considered an appropriate method. All records must be able to be readily available should the Agency or Police ask to view these.

3.4 Destroying waste material and products

Where the activities being undertaken by the licence holder include the disposal of unwanted or excess material (particularly seed heads, seeds, and flowers) this procedure must be documented.

It is expected that where the destruction involves other parties this is clearly included in the procedure document.

The method of disposal must render the material unusable, unrecognisable, and irretrievable. Cannabis material that has been rendered unusable, unrecognisable, and irretrievable via a treatment may be disposed of as general waste.

Section 4: Activity-specific guidance

This section provides guidance specific to completing the sections of the application form for the activities that are to be licensed on a medicinal cannabis licence.

For information on the activities for which the Agency can issue a medicinal cannabis licence, please see the *Guideline on the regulation of medicinal cannabis in New Zealand - Overview of the medicinal cannabis licensing scheme*.

4.1 Cultivation activity guidance

To apply for a licence that includes a cultivation activity, you must complete Section B of the application form.

Before applying for a cultivation activity, you must be able to demonstrate that you have organised an appropriate use for any plant material to be grown.

Where you intend to undertake other activities with the cultivated material you must ensure you are also licensed to undertake the relevant activity. For example, if you wish to extract constituents from cannabis you must have a possession for manufacture activity.

Should you not be able to demonstrate this, your application will be returned.

4.1.1 What you need to provide

Purpose

In your application, you are required to outline the purpose of your proposed cultivation activity. For example, you may be cultivating cannabis to supply other cultivators or for cultivation research, or to supply a manufacturer.

Sufficient information must be provided in your application (and any accompanying documents) to cover the scope of your operations from obtaining the seeds or plants through to the harvest and beyond.

Cultivars

The name and THC content of the cultivars you wish to grow must also be included. If a licence is issued to allow the cultivation of low THC cannabis and you wish to grow new cultivars, you can apply to amend your licence to allow this.

You are required to provide an estimate of the total area to be cultivated (in hectares) at each location. The following equations can be used to aid you in providing estimates in hectares.

Conversion of square metres to hectares:

$$Area\ (hectares) = \frac{Area\ (metres\ square)}{10{,}000}$$

Conversion of acres to hectares:

$$Area\ (hectares) = \frac{Area\ (acres)}{2.471}$$

4.1.2 Other regulatory guidance

Starting material for export

If you are intending to export your cultivated material, you will need to ensure that you have a supply activity on your medicinal cannabis licence. To apply for a supply activity to a new medicinal cannabis licence, please complete form F, or see section 6 to amend an existing licence to add a supply activity.

You will also need to apply for a licence to export controlled drugs for each consignment.

Export of samples for testing, analysis or research

Samples of starting material for testing, analysis, or research may be exported under a cultivation activity.

In order to do so, you will need to apply for an amendment to the cultivation activity on your medicinal cannabis licence to list the starting material for export. (Please see section 6 on amendments to medicinal cannabis licences).

As part of the amendment application, you will need to clearly demonstrate that the export is for testing, analysis, or research purposes, and that the amounts being exported are appropriate for that purpose. This could include evidence that the export is being sent to a testing facility and information on the quantities required to complete the testing.

You will also need to apply for a licence to export controlled drugs for each consignment.

Seeds, cuttings, rootstock, tissue for propagation and tissue culture for export

The export of seeds, cuttings, rootstock, tissue, and tissue culture is permitted under a cultivation activity.

You will also need to apply for a licence to export controlled drugs for each consignment.

4.2 Seed supply activity guidance

To apply for a licence that includes a seed supply activity, you must complete Section C of the application form.

4.2.1 What you need to provide

You must provide sufficient information in your application to cover the scope of your operations.

To import seeds, the licence holder will need to apply for a licence to import controlled drugs for each consignment.

To export seeds, the licence holder will need to apply for a licence to export controlled drugs for each consignment.

Imported seed must meet the biosecurity requirements under the Ministry for Primary Industries Import Health Standard – IHS 155.02.05 Seeds for Sowing:
https://www.mpi.govt.nz/importing/plants/seeds-for-sowing/

4.3 Research activity guidance

To apply for a licence that includes a research activity, you must complete Section D of the application form.

Important: If you are intending to supply or administer products to humans in the clinical trial or clinical study, the products must be made according to Good Manufacturing Practice (GMP) requirements. Further information on GMP is available on our website at:
https://www.medsafe.govt.nz/regulatory/Guideline/code.asp

You should not apply for this activity unless the Director-General of Health has approved your clinical trial, or Medsafe has advised that a clinical trial approval is not required for the trial applied for. For information on seeking approval to conduct clinical trials, contact Medsafe at:

askmedsafe@health.govt.nz and read clinical trials guideline *Part 11: Clinical trials – regulatory approval and good clinical practice requirements* at:
https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf

4.3.1 What you need to provide

You must provide a separate Section D for each location where the clinical trial will be conducted.

You must list the following people in Section D as 'responsible persons'.

- The person responsible for providing the medicinal cannabis product to the researchers.
- The principal investigator at each location where the clinical trial is being conducted (please also include a copy of the letter providing formal approval of the clinical trial).

In Section D, you must describe the security arrangements that you will put in place for keeping medicinal cannabis products secure until they are administered to the clinical trial participants.

4.4 Possession for manufacture activity guidance

To apply for a licence that includes a possession for manufacture activity, you must complete Section E of the application form.

4.4.1 What you need to provide

In your application, you must state the purpose of your proposed possession for manufacture activity. The information provided should include who you are planning to manufacture products for – such as patients (for this you also need to have a licence to manufacture medicines), a testing laboratory or a research facility.

You should provide an overview of your planned operations, from obtaining the starting material, cannabis-based ingredients, or other products, through to manufacturing, processing, packing, and testing. You should include enough detail to give a clear picture of the security precautions in place to ensure no product is diverted during each stage of your operation.

Other regulatory guidance

If you are intending to manufacture a cannabis-based ingredient or medicinal cannabis product intended for end use in a patient, you will need to ensure the manufacturing process complies with Good Manufacturing Practice (GMP) requirements. You will also need to hold a licence to manufacture medicines under the Medicines Act 1981.

4.5 Section F – Supply activity guidance

To apply for a licence that includes a supply activity, you must complete Section F of the form.

While an application can be submitted, a licence with a supply activity can only be issued for the supply of a cannabis-based ingredient or medicinal cannabis product when either:

- the ingredient or product is for supply within New Zealand and has been verified as meeting the minimum quality standard
- the ingredient or product is intended for export only, and the destination country has confirmed its willingness to accept the items.

The supply of CBD products is not able to be authorised by a supply activity on a medicinal cannabis licence. For information on the licensing requirements for the supply of CBD products within New Zealand please see *Guideline on the regulation of medicinal cannabis in New Zealand - Guidance for a new medicinal cannabis product application.*

4.5.1 What you need to provide

In your application, you need to provide a clear description of the purpose of your proposed supply activity. Include your role, such as a manufacturer, importer, cultivator, or exporter, and the sites at which supply activities (including storage and distribution) are to be undertaken under this licence.

You must provide an overview of your planned operations including the security precautions in place to ensure no product is diverted during each stage of your operation.

You also need to list any cannabis-based ingredients or other product you intend to supply. If you want to make any changes to this list in the future, you can apply to amend your licence to allow this.

If your ingredient or product is intended for export and does not meet the minimum quality standard, the tradename or unique identifier must be distinct from that of any product verified as meeting the minimum quality standard. This is to ensure transparency and prevent confusion between products intended for export only and those intended for domestic supply. For further information on the requirements of product names please see *Guideline on the regulation of medicinal cannabis in New Zealand - Guidance for a new medicinal cannabis product application.*

For an export only product you must also supply the name of the importing country, and evidence that the products have been produced under good manufacturing practice. Evidence that the importing country accepts the goods will be required to be submitted through the application process for a licence to export.

You must provide a recall plan for cannabis-based ingredients or medicinal cannabis products as part of your application. The recall plan must be in line with the requirements of, and reference the *New Zealand Medicines and Medical Devices Recall Code*.

Other regulatory guidance

If you intend to export or import cannabis material, cannabis-based ingredients, or medicinal cannabis products under your supply activity, you must obtain the appropriate import or export licence for each consignment.

If you are applying for a supply activity, you must be familiar with the requirements for the wholesaling of medicines under the Medicines Act 1981 and Medicines Regulations 1984.

Section 5: Standard operating procedures (or similar)

As part of your application for a medicinal cannabis licence, the Agency requires submission of standard operating procedures relating to security.

Whilst you are only required to submit the security procedures with your application, it is expected that you will have a robust quality management system in place, which includes SOPs which cover the activities you are intending to undertake.

Even once a licence has been issued, any changes to standard operating procedures that affect the security of the activities will require review by the Agency, and you should submit an application to amend the licence for that relevant activity.

5.1 Standard Operating Procedures expected to be in place

As a minimum, you must have standard operating procedures which cover the following (where applicable).

- Security protocols (for example, checks of the security measures at the facility at the start and end of each working day).
- Staff employment matters.
- Secure storage.
- Access to cannabis.
- Detection of unauthorised activity (for example, diversion, incidents, theft, stock discrepancies).
- Reporting of incidents / response.
- Transporting / receiving / shipping of cannabis material, cannabis-based ingredients, and products.
- Complaints / investigation and resolution.
- Product recall (including for export only cannabis) and management of recalled products.
- Management of cannabis waste.
- Record keeping procedures (stocktake).

You should ensure that procedures are in place for all aspects of your proposed operations.

Please note that as part of a good quality management system, all staff should be familiar with and trained in the procedures applicable to their roles.

Section 6: Amendment to a Medicinal Cannabis Licence

6.1 Changes requiring an amendment to a licence

The changes that require you to submit an application to amend your licence are specified in regulation 47 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and include:

- changes to the activities, or types of licenced activity, authorised on the licence
- a change at the location specified on the licence that may affect the security arrangements
- changing any responsible person.

Where you wish to move the location at which an activity is being undertaken you must:

- complete a licence amendment form to have the activity removed from your existing licence
- apply for the activity at the new location.

Please note that there must be at least one activity specified on your licence. If the change results in no activity on your licence, you must surrender your licence.

Other changes that require you to submit an application to amend the licence are where you intend to make significant changes to the following procedures:

- security protocols
- staff employment, training, termination
- secure storage
- access to cannabis
- detection of unauthorised activity (for example, possible diversion, incidents, theft, discrepancies of stock)
- reporting of incidents / response
- transporting / receiving / shipping of cannabis material, cannabis-based ingredients, and products
- management of cannabis waste
- record keeping procedures.

Changes of these types may affect the security of the operations and need to be approved before they can be made.

6.1.1 Adding and changing medicinal cannabis products listed on a Medicinal Cannabis Licence

You must submit an application to amend your licence where you wish to add an unverified product or cannabis-based ingredient intended for export only to the supply activity on your medicinal cannabis licence, or to make a change to an existing unverified product or ingredient.

You are not required to submit an application to amend your licence where you wish to add a verified product to the supply activity on your medicinal cannabis licence or to make a change to an existing verified product that is already listed.

However, whilst you do not need to submit an application to amend the licence, where the product requires verification against the minimum quality standard in order to be supplied, you must submit a New Medicinal Cannabis Product (NMCP) application or a Changed Medicinal Cannabis Product (CMCP) application.

For more information see the *Guideline on the regulation of medicinal cannabis in New Zealand: Guidance for a New Medicinal Cannabis Product Application* or the *Guideline on the regulation of medicinal cannabis in New Zealand - Guidance for a Changed Medicinal Cannabis Product Application.*

Once a new product, or changes to an existing product, have been verified to meet the minimum quality standard, an updated licence with the product details will be sent to you.

6.2 How to apply for an amendment to your licence

Note: where an amendment application is made and a licence granted, the expiry date of the amended licence remains the same as the original licence.

6.2.1 Submitting an amendment application

Applications to amend a licence must be made by completing and submitting Form LA: *Application to Amend a Medicinal Cannabis Licence* and attaching any required additional documentation.

The amendment application form requires you to provide information including:

- an application contact person
- details of the licence the application is seeking to amend
- details of the amendment you wish to make
- depending on the change you wish to make, you may be required to complete and include the appropriate activity sections of Form A: Application for a Medicinal Cannabis Licence (Sections B to F).

Some changes may require you to resubmit material you have previously provided to the Agency to support the application submitted (eg, floor plans of the facility, or standard operating procedures that have been updated since being provided).

Applications must be submitted to the Agency at least 60 working days before the proposed changes are to come into effect. The intended changes must not be made until approval is granted.

If you wish to make any changes after the application to amend your licence has been accepted for assessment, unless advised otherwise by the Agency, you will be required to withdraw your initial

application and submit a new application with all the requested changes. Depending on the nature and extent of the intended changes, fees may be charged for the new application.

Only one application will be accepted for consideration for amending a particular licence at any one time, however, more than one change can be requested on an individual application.

Should, following submission of an application, you wish to submit further amendment applications, you will be required to wait until a decision has been made on the existing application.

Please send your amendment application and all correspondence about your application to medicinalcannabis@health.govt.nz

6.2.2 Fees associated with an application to amend a medicinal cannabis licence

- There are fees associated with an application if you are applying for:
  - the addition of one or more new types of licensed activity to the licence
  - any change relating to a location used for a type of licenced activity if the change affects the location's security arrangements. This includes adding a location and changes to responsible persons.
- In the above situations, the following fees apply.
  - $345 (including GST) for the initial check of the application.
  - Where applicable, the assessment fee for the consideration of the changes. These are listed in section 1.3.3 of this guideline. This fee applies to:
    - the addition of a new activity
    - a change to the location that affects the location's security arrangements or cultivars grown at a location authorised for low THC cannabis only
    - changes to an existing activity that affect the security of the activity.

There is no additional assessment fee associated with an application to amend a medicinal cannabis licence to change any responsible person (including removal of a responsible person).

6.2.3 The process for the assessment of an amendment

The process for assessing an application to amend a medicinal cannabis licence is the same as that for assessing a new licence application (see section 1.2 of this guide).

If the amendment does not require payment of fees, then an initial check will not be required, and the application will be submitted for assessment.

Section 7: Changes to directors and partners

Changes to the composition of the board of directors or the partners must be notified to the Director-General at least 60 days before the change takes effect.

Applications to change the directors or partners of a licensed entity must be made by completing and submitting the DP form - Application to Change the Directors or Partners and attaching any required additional documentation, such as identification documents to enable a Ministry of Justice check to be conducted.

For information on the information required and the process for a Ministry of Justice check, please see section 2.3 of this document.

Applicable fees

- There is no initial check fee for removing a director or partner. However, the licence entity must have at least one director or two partners.
- There is an initial check fee of $345 (including GST) for adding (or replacing) directors or partners, but there is no assessment fee.

Section 8: Renewal of licence

Whilst medicinal cannabis licences are only able to be issued for a period of one year, a holder may apply to renew their licence on a yearly basis. An application to renew the licence must be made no earlier than 90 days, and no later than 30 days, before the expiry of the licence.

Applications that are received earlier than 90 days prior to the expiry of the licence will be returned.

Applications which are received within 30 days of the expiry of the existing licence will likely not allow sufficient time for the assessment of the application to be completed, and the existing licence will expire prior to being able to be renewed.

Fees for renewal of a licence are as stated in Section 1.3.3.

Please note that payment of fees is required prior to an application being accepted for assessment. It is the licence holder's obligation to ensure that fees are paid promptly.

Applications to renew a licence must be made by completing and submitting R Form: Application to Renew a Medicinal Cannabis Licence and attaching any required additional documentation.

Important: Only one application will be accepted and processed at a time. If you submit a licence amendment application and a renewal application around the same time, our priority will be on the renewal of the licence, so that you remain licensed. Therefore, you should consider delaying any licence amendment application until the licence has been renewed.

Section 9: Reporting obligations under a licence

9.1 Monthly returns for export or supply

Under regulation 70, a licence holder is to report monthly on any export or supply under a medicinal cannabis licence.

This means that any transaction of cannabis to a person authorised to receive it, including sending samples for testing, within New Zealand and by export must be reported to the Agency.

The return shall list the date, description of type of cannabis, quantity/volume, receiver details (name and address) and be sent to the Agency within seven days after the end of each month.

9.2 Annual Stocktake

Under regulation 67, reflecting the stock on 31 December each year, a licence holder must provide the following to the Agency by the end of the following month (ie, 31 January of the following year):

- a record of the actual amount of any cannabis, cannabis-based ingredient and medicinal cannabis product they possess at the time of the stocktake
- an account that compares the recorded amounts of the material that they possess with the actual amount at the time of the stocktake, including an explanation of any differences between the recorded and actual amounts.

9.3 Annual INCB reporting

The Agency is required to report annual estimates and statistics on cannabis to the International Narcotics Control Board (INCB).

This is part of the Government's responsibility to meet our international obligations under three international drug control conventions:

- the Single Convention on Narcotic Drugs 1961
- the Convention on Psychotropic Substances of 1971
- the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

You will be emailed a form to complete and the date for when the information is to be sent back to the Agency. For this purpose, you must provide details such as the total amount of each starting material, cannabis-based ingredient, and medicinal cannabis product that you propose to import and export for that year.

9.4 Obligation to report adverse reactions and safety issues associated with medicinal cannabis products

As medicinal cannabis products are medicines, holders of a medicinal cannabis licence with a supply activity have an obligation under section 41 of the Medicines Act 1981 to report any adverse reactions they have been made aware of. This includes information received from patients, health professionals (doctors and pharmacists), or manufacturers.

Adverse reactions should be reported to the Centre for Adverse Reaction Monitoring (CARM). A guide to adverse reaction reporting is available on the Medsafe website at: https://www.medsafe.govt.nz/profs/PUArticles/ADRreport.htm.

Any significant safety issues reported with a product should be reported to Medsafe.

Medsafe has produced a guidance document on Pharmacovigilance available at: https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/part-8-pharmacovigilance.pdf.

Section 10: Declaration of illicit seed and plants

The Regulations allow for holders of and applicants for a medicinal cannabis licence with cultivation activities to declare their intention to procure plants or seeds established in New Zealand from a non-licensed source for the purpose of cultivation.

You may only submit a declaration of illicit seed and plants if your licence authorises the cultivation of high THC cultivars. Should your licence authorise multiple sites, the cultivation activities associated with the seed and plants obtained in accordance with the declaration must be conducted only at the site authorised for high THC cultivars.

To make a declaration, you must complete Form D: Declaration of illicit seed and plants.

Please note that the declaration of a variety of cannabis under Regulation 35 of the Regulations does not grant plant variety rights under the Plant Variety Rights Act 1987. For more information on plant variety rights, see https://www.iponz.govt.nz/about-ip/pvr/.

10.1 Fee for a declaration of illicit seed and plants

Activity	Fee per declaration (including GST)
Declaration of illicit seed and plants	$747.50

If you submit a declaration of illicit seed and plants with your application, and a licence is not able to be issued, the fee for the declaration is not refunded.

Note: a declaration of illicit seed and plants will only be accepted after a licence has been issued.

Appendix 1: Tools to support development of a security plan

Note: You should only use these tools to help you to develop a security plan. Do not include them in your application. They also may not specify all the information that you need to include in a plan.

Australian Office of Drug Control Guideline: Security of Medicinal Cannabis

The Australian Office of Drug Control has published guidance to help licence applicants to design and meet Australia's security standards. You can use it as a starting point for the information that you should cover in a security plan. For more information, go to:
https://www.odc.gov.au/publications/guideline-security-medicinal-cannabis

Questions to consider when developing your security plan

The table below identifies questions relevant to meeting the requirements of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and suggests some appropriate ways of responding to them.

Q	Regulation reference*	Question(s)	Applicant response	Reference document(s)
1	32(3)(b)	What do the premises look like? What are the physical security arrangements?	[Provide a location plan and a floor plan of any buildings if applicable.]	[Attach a location plan and a floor plan of any buildings if applicable.]
2	32(3)(b)	What are the procedural security arrangements? How and where do you handle cannabis and/or cannabis products and store them on the premises?	[With reference to the plan(s) provided for Q1, indicate the areas where cannabis and/or cannabis products, including waste materials, will be stored and handled.]	[Attach any standard operating procedures or documents needed to demonstrate measures in place.]
3	32(3)(b)	What are the arrangements for security of staff?	[Describe the measures in place and how these measures achieve the level of staff security required.]	[Attach any standard operating procedures or documents needed to demonstrate measures in place.]
4	56(1)	What prevents the public from accessing cannabis materials?	[Provide a list of the features of the premises that prevent public access. Provide a description detailing how these features prevent public access. Examples may include physical features such as fences and gates.]	[Attach a location plan and a floor plan if applicable, with any physical features you refer to in your description]
5	56(1)	How do you manage visitor access to the premises? What prevents visitors from accessing cannabis materials?	[Describe the measures in place and how these measures control visitor access to the premises.]	[Attach any standard operating procedures or documents needed to demonstrate measures in place.]

Q	Regulation reference*	Question(s)	Applicant response	Reference document(s)
6	56(1)	What will stop intruders from accessing the cannabis materials?	[Describe the measures in place and how these will protect the materials from intruders. This may include physical features, procedures, controls on equipment or buildings.]	[Attach any procedures or other documents you refer to in your description.]
7	55(1)(b)	What measures are in place to control and monitor staff access to cannabis and/or cannabis products?	[Describe the measures and how they control and monitor staff access to cannabis and/or cannabis products.]	[Attach any procedures or other documents you refer to in your description.]
8	57	What measures are in place to detect unauthorised access to the location and theft of cannabis and/or cannabis products?	[Describe what measures are in place and how they detect unauthorised access or theft. This should include any measures to detect the unauthorised access at the time it is occurring and any measures to detect the unauthorised access or theft after the fact.]	[Reference any relevant procedures and attach information about them along with relevant diagrams to support your response.]
9	57	What procedures are in place to deal with theft or loss?	[Describe the step-by-step actions that you will take if theft or loss occurs. This should include an indication of when you will inform police and the Medicinal Cannabis Agency of the theft or loss.]	[Reference and attach information about relevant procedures.]

* Requirements under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

The next table deals with questions specific to the security requirements for the cultivation activity.

Q	Regulation reference	Question	Applicant response
10	56(2)	What measures are in place to address the risk of dispersal of the cannabis from the licence location?	[Describe how you manage risk.]
11	56(2)	For outdoor cultivation of cultivars that are not approved industrial hemp cultivars: What measures are in place to address the risk of cross-pollination from your medicinal cannabis to any industrial hemp crops in the vicinity?	[Describe how you manage risk.]
12	56(1)	For outdoor cultivation of cultivars: What measures are in place to protect the plants from animal access?	[Describe how you manage risk.]

* Requirements under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.