MEDICINAL CANNABIS AGENCY

MINISTRY OF HEALTH
MANATŪ HAUORA

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 1

1.1 Licensing framework 1

1.2 Application fees 2

1.2.1 Initial check 2

1.2.2 Application and renewal fees 2

1.2.3 Activity fees 2

1.2.4 Example of how to calculate application fees 3

1.3 Licensing process 3

Section 2: Overview of the Medicinal Cannabis Licence application form 6

2.1 Structure of Medicinal Cannabis Licence application form 6

2.2 Section A – applicant information 7

2.2.1 Eligibility to hold a licence – individual 7

2.2.2 Applicant details – individual 8

2.2.3 Eligibility to hold a licence – entity 8

2.2.4 Applicant details – entity 8

2.3 Eligibility to be a responsible person 9

2.4 Request for criminal conviction history 9

2.5 Statutory declaration 10

Section 3: Completing the application form for a medicinal cannabis activity 11

3.1 The location or locations for each activity 11

3.1.1 Being entitled to use the location 11

3.2 Security arrangements at the location 12

3.3 Tracking and record keeping 13

3.4 Destroying waste material and products 13

3.5 Transporting cannabis material 13

Section 4: Activity-specific guidance 14

4.1 Section B – cultivation activity guidance 14

4.1.1 What you need to provide 15

4.1.2 Bulk starting material for export 15

4.2 Section C – nursery activity guidance 15

4.2.1 What you need to provide 16

4.3 Section D – research activity guidance 16

4.4 Section E – possession for manufacture activity guidance 17
4.4.1 What you need to provide 17
4.5 Section F – supply activity guidance 18
4.5.1 What you need to provide 18

Section 5: How to make a declaration of illicit seed 20

Appendix 1: Tools to support development of a security plan 21

Section 1: Introduction

This guidance document is **Part 4: Guidance for Applicants for a Medicinal Cannabis Licence** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*. Its purpose is 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 Parts 1 to 5 of the Guideline in full.

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

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

1.1 Licensing 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:

1. a cultivation activity
2. a nursery activity
3. a research activity
4. a possession for manufacture activity
5. a supply activity.

Under the licensing framework, you can submit a single application to conduct whichever activity or combination of activities you wish to be licensed for. This approach reduces the overall administrative burden on applicants.

The Medicinal Cannabis Licence can cover one of the following:

- one activity at one location only
- one or more activities at the same location
- one or more activities at different locations.

You must apply for at least one activity to be specified on your Medicinal Cannabis Licence in your initial application. You can apply to add an activity to your licence at any time after the Medicinal Cannabis Agency (the Agency) has issued you a licence, when you pay the application fee for the activity. If the Agency approves your application, your licence will be amended to include the additional activity.

In considering your application, the Agency assesses how you will manage the activities you wish to carry out under the licence. It also assesses each location where you will carry out these activities, which includes inspecting all of these locations to check that adequate security arrangements are in place.

Another part of the assessment process is to check the eligibility of an individual applicant or, if the applicant is a body corporate or partnership, of any directors, partners and responsible persons involved in the application.

For more information on the licensing framework, see **Part 1: Licensing Scheme Overview** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

1.2 Application fees

The application fees reflect the cost of processing applications and carrying out inspections of the locations of each activity.

The full fee for a licence application will depend on the activity (or activities) you wish to carry out. Fees will not be refunded if the Agency declines an application after an assessment.

You must also pay an application fee when you apply for a licence to be renewed.

Do not include payment with your application. You will be invoiced when we receive your application. We will only accept payments made on invoices issued.

All fees below are in New Zealand dollars and include goods and services tax (GST).

1.2.1 Initial check

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

When we receive your application, we will send you an invoice for the initial check, which involves ensuring that you have completed your application in full and that it is ready for assessment. The initial check will not be carried out until you have paid the invoice.

The fee for the initial check is non-refundable and is charged for each application, no matter how many activities you are applying for. This fee also applies if you want to add an activity to your licence or if you want to renew your licence.

1.2.2 Application and renewal fees

Medicinal Cannabis Licence application fee: $2,587.50 (including GST).

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

All licence applicants must pay the Medicinal Cannabis Licence application fee.

1.2.3 Activity fees

We will charge a fee for each activity or location that you wish to be covered under your Medicinal Cannabis Licence. If you wish to apply for the same activity at two separate locations, you need to pay two activity fees. 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 **Part 1: Licensing Scheme Overview** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.
- 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 **Part 1: Licensing Scheme Overview** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* for more information on these licences.

Fees for different types of activities under a Medicinal Cannabis Licence

Activity	Activity fee per location (including GST)
Cultivation	$5,462.50 new $3,392.50 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
Nursery	$747.50 new $747.50 renewal

1.2.4 Example of how to calculate application fees

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 applicant must pay a total of $20,240 (including GST):

- $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).

1.3 Licensing process

The licensing process involves four major steps, as we describe below. The flowchart that follows sums up this process.

Step 1: Initial check of application

When we receive your application, we will invoice you for $345 (including GST) for an initial check of your application. We will carry out the initial check once you have paid the invoice.

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 and pay another fee for another initial check.

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

You must pay the fee for the licence and the fee for each activity that the licence will cover before we can consider your application for assessment. Once you have paid the full fee, we will accept your application for assessment.

While assessing your application, the Medicinal Cannabis Agency may request additional information or clarification of the information provided. We will not be able to progress your application any further until you provide the requested information or clarification.

You cannot change your application once assessment has started. If you need to make any changes, you will need to discuss these with us. You can make minor changes such as correcting a phone number or mis-spelt address details. If you want to make substantial changes that may affect the outcome of the application or require reassessment, such as changes to responsible persons or location information, we may ask you to submit a new application and to pay the relevant application fee again.

For this reason, it is important that when you submit your application to the Agency, you include as much information as possible and that you ensure you are not likely to make any changes.

Step 3: Inspecting the location

Once we have assessed your application and are satisfied that you have met the requirements, you will need to confirm that the security arrangements are in place and that the location or facility is ready for inspection. If you will be carrying out one or more activities at more than one location, then each location will need to be inspected.

You must provide at least one month’s advance notice to schedule the inspection.

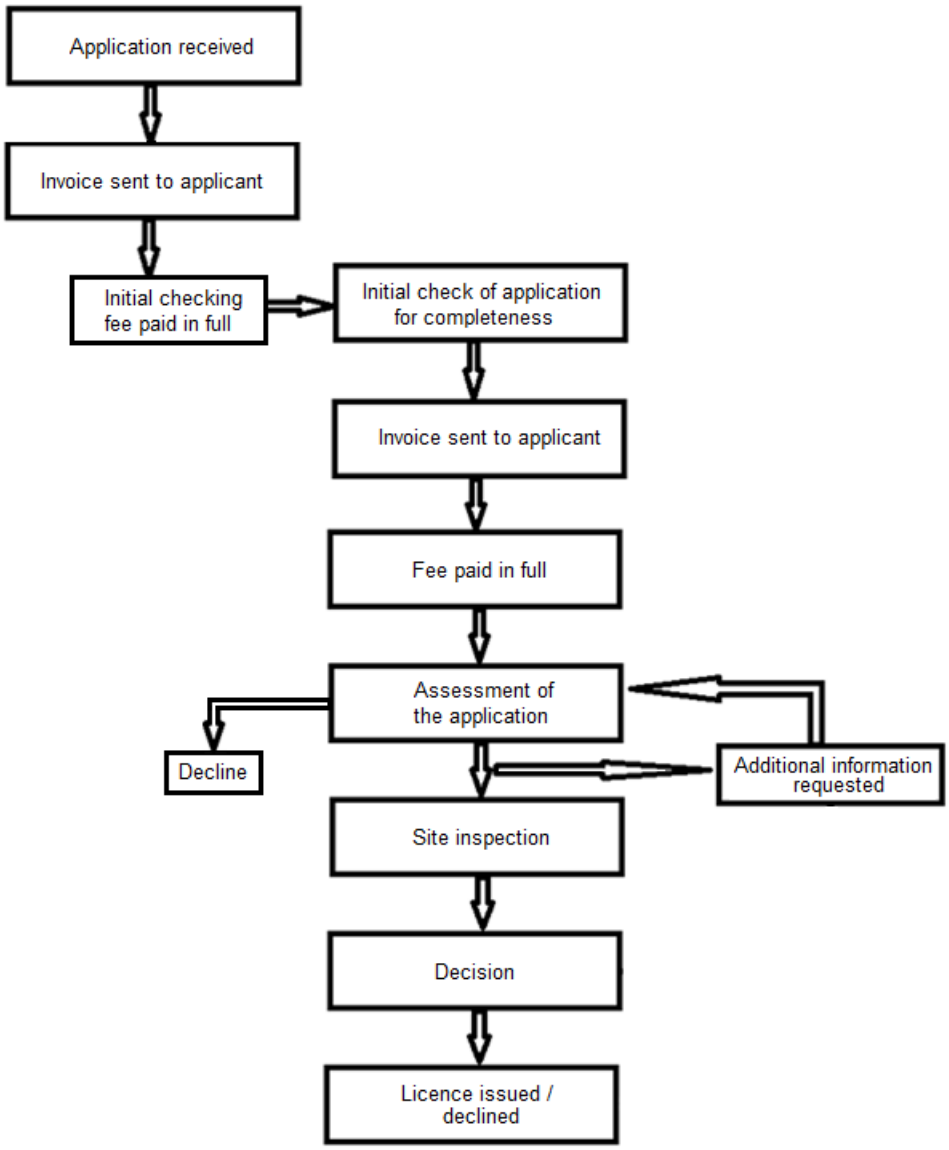
We will not issue a licence until each location has been inspected and you have addressed all issues identified during the inspection.

Step 4: Issuing a Medicinal Cannabis Licence

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

We issue a Medicinal Cannabis Licence for one year unless it is renewed or terminated sooner.

Summary of the licensing process



Your licence fee will not be refunded if your application is declined.

If we decline 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 our decision. The reviewer will carry out the review in line with regulation 41 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

Section 2: Overview of the Medicinal Cannabis Licence application form

The application form for a Medicinal Cannabis Licence requires you to supply information on the:

- applicant – giving details for an individual or an entity (body corporate or partnership)
- types of activities that the licence you are applying for will cover.

You must submit your application to the Agency on **Form A: Application for a Medicinal Cannabis Licence** and include all the supporting information requested on the form. You should also keep a copy of your application for your records.

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.

For an electronic submission, scan the completed application form and supporting documents and email the scanned files to medicinalcannabis@health.govt.nz

If you are unable to scan and email the application form and supporting documents, you can post a copy to:

Medicinal Cannabis Agency
Ministry of Health
PO Box 5013
Wellington 6145

2.1 Structure of Medicinal Cannabis Licence application form

The application form for a Medicinal Cannabis Licence contains six sections.

- Section A: Application for a Medicinal Cannabis Licence
- Section B: Cultivation activity
- Section C: Nursery activity
- Section D: Research activity
- Section E: Possession for manufacture activity
- Section F: Supply activity.

All applicants must complete Section A: Application for a Medicinal Cannabis Licence.

Among the other sections (B to F), you must complete the sections that are relevant to each activity you wish to apply for. You do not need to complete the sections that are not relevant to your application.

Complete an additional copy of each 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.)

Once you have completed the appropriate sections, submit your application along with any additional supporting documents.

2.2 Section A – applicant information

All applicants must complete Section A of the application form. This section:

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

For details on applying for a licence as an individual, go to Sections 2.2.1 and 2.2.2.

For details on applying for a licence on behalf of an entity, go to Sections 2.2.3 and 2.2.4.

2.2.1 Eligibility to hold a licence – individual

To hold a Medicinal Cannabis Licence as an individual, you must be 18 years or older and live in New Zealand. You must also be familiar with, and have the expertise and resources to comply with, the obligations the Regulations place on the licence holder for the types of licensed activity you are applying for.

Individual applicants must not have:

- had a licence issued under the Misuse of Drugs Act 1975 or any regulation[1] made under that Act that has been revoked
- had a conviction under the Misuse of Drugs Act 1975[2] or any other drug-related offence
- been convicted of a crime involving dishonesty within the meaning of the Crimes Act 1961[3]
- been convicted of an offence overseas that, if committed in New Zealand, would be an offence under the above legislation.

A licence may be issued to an individual who would otherwise be ineligible due to a conviction or the prior revocation of a licence on a discretionary basis. Further approval is necessary as part of this process. Individuals with relevant convictions may wish to submit additional information with their application to explain why they should be eligible for a licence.

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.

[1] Misuse of Drugs Regulations 1977; Misuse of Drugs (Industrial Hemp) Regulations 2006; Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

[2] Offences against the Misuse of Drugs Act 1975 include the manufacture, supply or possession of illicit substances, and the possession of utensils.

[3] A crime involving dishonesty as described in the Crimes Act 1961 describes a crime involving dishonesty. It generally includes theft, fraud, receiving, conversion, corruption, bribery, trading in influence and corrupt use of information.

2.2.2 Applicant details – individual

The applicant is the contact person the Agency will communicate with on all matters to do with the licence application. You should inform the Agency of any changes to contact details (phone number, email address or postal address).

2.2.3 Eligibility to hold a licence – entity

For an entity to hold a Medicinal Cannabis Licence, all directors or partners of the entity must be 18 years or older.

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

One or more directors or partners of the entity must have the expertise, and the 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.

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
- 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.

A licence may be issued to an individual who would otherwise be ineligible due to a conviction or the prior revocation of a licence on a discretionary basis. Further approval is necessary as part of this process. In these cases, the entity may wish to submit additional information with their application to explain why it should be eligible for a licence.

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.

2.2.4 Applicant details – entity

The entity's contact person is the person who is authorised to communicate with the Agency on all matters to do with the licence application. This person should have the authority and ability to answer questions about the application. They should inform the Agency of any changes to contact details (phone number, email address or postal address).

The details the entity must provide are:

- its contact details – name of contact person, phone number and email address
- the name of the body corporate, partnership or organisation
- its New Zealand Companies Office company registration number – a body corporate must be incorporated in New Zealand to be eligible for the licence

- its physical (street) address
- its postal address – if the postal address is the same as the physical address, tick the box provided rather than giving the details again
- the full name of each of its directors or partners.

2.3 Eligibility to be a responsible person

If the licence holder 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 and with any conditions the licence imposes. The entity may nominate different people as the responsible person for each activity and/or location.

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

Responsible persons **must** be 18 years or older and live in New Zealand.

Responsible persons **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.

An individual may be approved as a 'responsible person' even if they have had a licence revoked or an applicable conviction on a discretionary basis. Further approval is necessary as part of this process. In these cases, the applicant may wish to submit additional information with their application to explain why the individual should be approved as a responsible person.

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 submit the requests to the Ministry of Justice when it has accepted the application for full assessment. The Agency will not accept Ministry of Justice criminal conviction reports that the applicant has obtained.

To enable the Agency to arrange for criminal conviction checks, each individual applicant, director, partner or nominated responsible person must fill in steps 2–4, and may need to fill in step 5 (see below), on the Ministry of Justice form *Request for criminal conviction history – third party*: https://www.justice.govt.nz/criminal-records/get-someone-elses/

Along with the request form, you must provide the necessary identification. That identification must:

- be a clear and readable copy
- exactly match the details in the form – the person's name on the form must be exactly as it appears on their identification
- not be defaced
- 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 any of the above forms of identification, they will need to ask someone to confirm their identity by filling in step 5 on the form.

For guidance on how to fill in the form, go to the Ministry of Justice's website at: https://www.justice.govt.nz/assets/Documents/Publications/completing-request-for-criminal-conviction-history-3rd-party2.pdf

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

If you have an electronic signature facility such as a Digital ID file, you may use this for the application and submit the application by email.

If you do not have an electronic signature facility, you may sign and scan the application, and submit the scanned application by email.

If you submit your application as a hard copy then the application can be physically signed and submitted to the Agency via the post.

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

You must apply for medicinal cannabis activities on the relevant sections 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 **Part 1: Licensing Scheme Overview** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

3.1 The location or locations for each activity

A Medicinal Cannabis Licence authorises an activity in 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.

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
- physical security, security of operational procedures and personnel security arrangements.

You should describe 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 staff and visitors are authorised to be in the location and to minimise theft or misappropriation.

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

The Agency's assessment of the security arrangements involves both a desktop assessment of your application and an onsite inspection of each location to verify that appropriate security arrangements are in place and operational.

We only consider our assessment of your application to be complete when an inspection of the location has verified that you have adequate security arrangements in place. We cannot issue a licence until this has occurred.

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

If you intend to cultivate only approved industrial hemp (low THC) cultivars, then we would have significantly lower expectations around intruder resistance and access controls than if you are planning to cultivate non-approved cannabis cultivars. If you intend to cultivate high-THC cultivars or cultivars with unknown or mixed THC levels, then you will need to have a higher level of security.

Appendix 1 contains tools to help you to develop a security plan. You can use them as a guide but be aware they may not contain all the information necessary for a security plan in all cases. You

may find it useful to engage 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 that you:

- cultivate
- maintain for the purpose of propagation
- produce, possess and store
- supply within New Zealand to another licence holder
- administer under a licence
- 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
- the amount of cannabis, cannabis material or products you possess at the time of stocktake.

In your application, you should 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 from seed or cutting, through to harvest, drying and processing, through extraction or manufacture, or through supply or administration. Those arrangements should include accounting for destruction or disposal of any plant material or product.

You can keep records electronically or on paper. You should use a secure method of recording and you must ensure that records cannot be tampered with or destroyed. You should consider the means for backing up records. You should also be able to produce your records for viewing if the Agency requests it.

3.4 Destroying waste material and products

You must outline your procedures for disposing of all unwanted or excess material (particularly seed heads, seeds and flowers) in a way that renders the material unusable, unrecognisable and irretrievable. This includes documenting procedures for destruction and any third-party arrangements for destruction and disposal of waste material.

3.5 Transporting cannabis material

If your procedures involve transporting cannabis material, you need to become familiar with the requirements of regulation 23 of the Misuse of Drugs Regulations 1977. These requirements cover written authority, endorsement of receipt, and delivery arrangements. If you meet these requirements, the carrier is not required to hold a Licence to Deal in Controlled Drugs.

Section 4: Activity-specific guidance

This section provides guidance specific to each of the activities you can apply for a licence for. Use it alongside Section 3 to help you complete the relevant activity section or sections in the application form. It is important to familiarise yourself with what you are authorised to do under each activity so that you apply for the correct activities for your purpose.

For more details on the activities for which the Agency can issue a Medicinal Cannabis Licence, see **Part 1: Licensing Scheme Overview** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

4.1 Section B – cultivation activity guidance

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

The processing of cannabis plant material allowed under a Medicinal Cannabis Licence where cultivation is a specified activity is limited to physical processes such as harvesting, collection, trimming or discarding, and drying.

The cultivation activity does not allow you to extract, grind or mill constituents from cannabis. To extract, grind or mill these constituents, you must have a 'possession for manufacture' activity specified on your licence.

Remember that you may only obtain source material for the cultivation activity:

- from another licence holder
- by importing seeds (under an import licence) from a supplier in a country that allows export under licence
- from the holder of an industrial hemp licence (limited to 50 seeds and 20 plants)
- by making a declaration of illicit seeds or plants (limited to 50 seeds and 20 plants) of a variety that is established in New Zealand.

If you hold a licence to cultivate a prohibited plant for scientific or medical research, you may carry over all your imported seeds and no more than 50 cannabis plants to your medicinal cannabis licence with cultivation activity for the purpose of cultivation.

Imported seed must meet 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/ (see section 2.14, page 28 of the Import Health Standard).

No one can import cannabis plant material until the Ministry for Primary Industries has published an Import Health Standard for cannabis plants.

4.1.1 What you need to provide

In your application, you should 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. Indicate whether you intend to undertake any of these activities yourself or whether you have an agreement to supply cannabis to the holder of another licence. Provide a copy of the agreement if possible.

You should provide sufficient information in your application to cover the scope of your operations from obtaining the seeds or plants through to the harvest and beyond. You should describe the nature of the operating procedures in enough detail so that someone else can understand and follow the steps in any particular procedure.

You must list the name and THC content of the cultivars you wish to grow. In the future, if you wish to grow new cultivars, you can apply to amend your licence to allow this.

One of New Zealand's obligations under the United Nations Drug Control Conventions is to provide estimates of the amount of cannabis and cannabis products that are produced in and imported into New Zealand annually. For this purpose, you must provide details of the predicted total amount (in kilograms) of cannabis you propose to cultivate for the year that this licence is issued, and the cultivation area (in hectares) at each location. The information you provide will only be used for reporting purposes.

How to convert square metres to hectares:

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

How to convert acres to hectares:

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

4.1.2 Bulk starting material for export

To export bulk starting material, you will need a licence that also specifies the supply activity, and each export consignment will need to be verified to have met the minimum quality standard. For more information on the minimum quality standard, see **Part 3: Guidance for a New Medicinal Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

4.2 Section C – nursery activity guidance

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

The holder of a licence with the nursery activity may import, purchase and supply seeds to another licence holder for cultivation.

A nursery activity does not by itself allow the licence holder to deal in cannabis plants but may be appropriate for a licence holder who intends to act as a 'seed merchant' only. The nursery activity

does not authorise you to cultivate plants for supply; to do this, you need a licence that specifies the cultivation activity.

To import seeds, the licence holder will need to apply for an import licence for each consignment. For further information about import licences, see **Part 1: Licensing Scheme Overview** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

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/ (see section 2.14, page 28 of the Import Health Standard).

4.2.1 What you need to provide

You should provide sufficient information in your application to cover the scope of your operations. You should describe the nature of the operating procedures in enough detail so that someone else could understand and follow the steps in any particular procedure.

One of New Zealand's obligations under the United Nations Drug Control Conventions is to provide estimates of the amount of cannabis and cannabis products that are produced in and imported into New Zealand annually. For this purpose, you must provide details of the total amount of cannabis seed you propose to import for the year that the licence is issued. The information you provide will only be used for reporting purposes.

4.3 Section D – research activity guidance

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

The holder of a licence with the research activity may supply medicinal cannabis products (that are not CBD products) to participants in a clinical trial.

You should not apply for this activity unless the Director-General of Health has approved your clinical trial. 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

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 should 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.

You must keep comprehensive records, including a register of the amount of cannabis product you possess, supply or administer as part of the clinical trial.

4.4 Section E – 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.

You must hold a medicinal cannabis licence for a possession for manufacture activity if you wish to manufacture a medicinal cannabis product. You can no longer carry out this activity under a licence to deal in controlled drugs.

Possession for manufacture allows the following activities:

- extracting constituents from cannabis material
- grinding or milling dried cannabis product
- manufacturing starting material
- manufacturing a cannabis-based ingredient
- manufacturing a dried product
- manufacturing a dosage product
- packing
- labelling
- testing cannabis material, ingredients and products for a therapeutic purpose.

If you are intending to manufacture a finished product for patients to use, you will need to ensure the product meets the medicinal cannabis minimum quality standard and complies with Good Manufacturing Practice (GMP) requirements. You will also need to hold a licence to manufacture medicines under the Medicines Act 1981.

For more information, see:

- https://www.medsafe.govt.nz/Medicines/manufacturing.asp
- **Part 2: Information for New Zealand Manufacturers and Packers** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*
- **Part 3: Guidance for a New Medicinal Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

4.4.1 What you need to provide

In your application, you should outline the purpose of your proposed possession for manufacture activity. Include who you are planning to manufacture products for – such as patients, 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 product, 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.

One of New Zealand's obligations under the United Nations Drug Control Conventions is to provide estimates of the amount of cannabis and cannabis products that are imported into New Zealand annually. For this purpose, you must provide details of the total amount of each

individual starting material, cannabis-based ingredient and/or medicinal cannabis product that you propose to import for the year that this licence is issued. The information you provide will only be used for reporting purposes.

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.

The holder of a licence with the supply activity may supply medicinal cannabis products to others who hold an appropriate licence. The supply activity only allows you to supply the products that are included on the licence.

Where an importer of medicinal cannabis products distributes them from a holding warehouse, the licence must record the warehouse as a supply location.

To get a new product included under your supply activity, you need to submit information about the product to the Agency. We will assess this information to verify that it meets the quality standards or is confirmed to be exempt from meeting the quality standards.

If you intend to only supply products that have already been assessed as complying with the quality standard, please contact the Agency to discuss your operation. A licence to deal in controlled drugs may be more appropriate in some circumstances.

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

The supply activity does not cover the wholesale supply of CBD products, as these products are no longer controlled drugs but remain prescription medicines. Supply of CBD products is covered by a Licence to Sell Medicines by Wholesale issued under the Medicines Act 1981. CBD products also require an assessment to verify that they meet the quality standards.

4.5.1 What you need to provide

In your application, you need to outline the purpose of your proposed supply activity. Include your role, such as a manufacturer, importer, cultivator or exporter.

You should provide an overview of your planned operations. 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.

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.

You must supply a medicines recall plan as part of your application. You may wish to use the *New Zealand Medicines and Medical Devices Recall Code* as a starting point when creating a recall plan appropriate to your situation.

One of New Zealand's obligations to the United Nations Drug Control Conventions is to provide estimates of the amount of cannabis and cannabis products that are imported into New Zealand annually. For this purpose, you must provide details of the total amount of each medicinal cannabis product and cannabis-based ingredient that you propose to import for the year that this licence is issued. The information you provide will only be used for reporting purposes.

Section 5: How to make a declaration of illicit seed

The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 allow for holders of and applicants for a Medicinal Cannabis Licence with cultivation activities (and holders of a licence to cultivate a prohibited plant that is held at 1 April 2020) to declare their intention to procure plants or seeds established in New Zealand from a non-licensed source for the purpose of cultivation.

To make a declaration, you must complete **Form D: Declaration of illicit seed and plants.** The fee for making a declaration is $747.50 (including GST).

In the application, you must identify the number of plants and seeds that you wish to declare and the name of the cannabis variety. The plants and seeds must be from a variety already established in New Zealand.

You can declare up to 20 plants **and** 50 seeds on a single declaration form. If you require a further quantity, you must submit another declaration and pay the fee for it.

Please note that the declaration of a variety of cannabis under regulation 35 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 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/

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)	For outdoor cultivation only: What measures are in place to address the risk of dispersal of the plants from the cultivation area?	[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.