MEDICINAL CANNABIS AGENCY

MANATŪ HAUORA
MINISTRY OF HEALTH

GUIDELINE ON THE REGULATION OF MEDICINAL CANNABIS IN NEW ZEALAND

Overview of the medicinal cannabis licensing scheme

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Section 1: Introduction

This document is the ***Guideline on the regulation of medicinal cannabis in New Zealand: Overview of the medicinal cannabis licencing scheme***. It provides you with an overview of the licensing regime under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations), and the other licences relevant to medicinal cannabis under the Medicines Act 1981 and the Misuse of Drugs Regulations 1977.

We recommend that you read all our ***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.

Should wish to contact us, please email us at: medicinalcannabis@health.govt.nz.

1.1 The Medicinal Cannabis Scheme

The Regulations establish the Medicinal Cannabis Scheme (the Scheme). The purpose of the Scheme is to improve access to quality medicinal cannabis products for patients through:

- enabling the commercial cultivation of medicinal cannabis and the manufacture of medicinal cannabis products in New Zealand
- setting a standard of quality for medicinal cannabis products (the minimum quality standard) so that medical practitioners can prescribe them with confidence in their quality and consistency.

The body of the Regulations is divided into two parts. Part 1 sets out the requirements for the minimum quality standard that medicinal cannabis products covered by the Scheme must meet. Part 2 sets out the requirements for medicinal cannabis licences and activities enabled by the Scheme.

1.2 The Medicinal Cannabis Agency

The Medicinal Cannabis Agency (the Agency) has been established within the Ministry of Health to administer the Scheme. The functions of the Agency include:

- overseeing the licensing of cultivators, manufacturers, suppliers and researchers of medicinal cannabis products
- monitoring compliance with licensing conditions, including the requirements for cannabis products to meet the minimum quality standard
- post-market monitoring of medicinal cannabis products
- collecting and reporting data to the International Narcotics Control Board about medicinal cannabis production and use in New Zealand
- providing advice to the public and interested parties about the Scheme.

1.3 The New Zealand Medicines and Medical Devices Safety Authority – Medsafe

In New Zealand, medicinal cannabis is controlled by both the medicines and misuse of drugs legislation, as some medicinal cannabis products are both medicines and controlled drugs. The Medicines Act 1981 and the Misuse of Drugs Act 1975 are administered by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). Further information on Medsafe can be found at: www.medsafe.govt.nz.

Section 2: Regulation of Medicinal Cannabis

2.1 Medicinal cannabis products and ingredients

The meanings of cannabis, starting material, cannabis-based ingredient, and medicinal cannabis product are defined in the Regulations.

Cannabis means—

(a) any part of any plant of the genus *Cannabis*; and

(b) any fruit or seed of such a plant

Starting material means—

(a) fresh or dried cannabis that is intended to undergo further processing and be used in, or for, a medicinal cannabis product; and

(b) initial extracts from cannabis intended to undergo further processing or extraction and be used in, or for, a cannabis-based ingredient

Medicinal cannabis product means a product—

(a) that—

  (i) is dried cannabis; or

  (ii) contains 1 or more cannabis-based ingredients and is in a pharmaceutical dosage form (such as a tablet, a capsule, or an oral liquid); and

(b) that contains no prescription medicine (as defined by section 3 of the Medicines Act 1981) or controlled drug other than cannabis or a cannabis-based ingredient; and

(c) whose purpose is therapeutic, rather than recreational or anything else

Cannabis-based ingredient—

(a) means an ingredient that—

  (i) is extracted from cannabis; and

  (ii) is intended to be used in, or for, a dosage product; and

(b) includes dried cannabis that is intended to be used in, or for, a dosage product.

2.2 Licensing for medicines and controlled drugs

The type of licence you require depends on the specific activities you wish to undertake and the classification of the product(s) you are working with.

Medicinal cannabis activities are regulated by both the:

- *Misuse of Drugs Act 1975*
- *Medicines Act 1981.*

Medicinal cannabis products and cannabis-based ingredients are primarily controlled under the Medicines Act if they meet the definition of a CBD product, or by both the Medicines Act and the Misuse of Drugs Act where the product is a controlled drug.

Information on medicinal cannabis licences under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 can be found in Section 3: Medicinal cannabis licence.

Information on licences under the Medicines Act can be found in Section 4: Licences issued under the Medicines Act 1981.

Information on other licences you may require under the Misuse of Drugs Act can be found in Section 5: Licences issued under the Misuse of Drugs Regulations 1977.

2.3 Cannabidiol (CBD) products

Products that meet the definition of a *CBD product* in *section 2A* of the Misuse of Drugs Act 1975 are classified as prescription medicines.

CBD is known to have little to no psychoactive effect, and there is no restriction on the amount of CBD in a CBD product. However, the amount of other cannabinoid substances with psychoactive properties (such as THC) in a product must be demonstrated to fall below a defined level to meet the definition of a CBD product and not be classified as a controlled drug.

More information on what is and what isn't a CBD product can be found on the Ministry of Health website at: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-industry/medicinal-cannabis-agency-working-medicinal-cannabis/medicinal-cannabis-agency-cannabidiol-cbd-products.

The supply or manufacture of CBD products must be specifically authorised by a licence under the Medicines Act 1981 (See Section 4: Licences issued under the Medicines Act 1981 for more information).

The licence requirements for CBD products differ from other medicinal cannabis products which are controlled drugs. However, all medicinal cannabis products (including cannabis derived CBD products), that have not been granted consent through Medsafe's evaluation and approval process, must meet the minimum quality standard set out in Part 1 of the Regulations before they can be supplied within New Zealand.

Information on the requirements of the minimum quality standard can be found in the Guidelines on the regulation of medicinal cannabis in New Zealand on our website at: https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms.

2.4 Medicinal cannabis products that are controlled drugs

Medicinal cannabis products that do not meet the definition of a CBD product are classified as controlled drugs under the Misuse of Drugs Act 1975.

Where the product is a controlled drug, and is used for a therapeutic purpose, it is also classified as a prescription medicine under the Medicines Act 1981.

Section 3: Medicinal cannabis licence

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 activities:

1. Cultivation activity.
2. Seed supply activity.
3. Research activity.
4. Possession for manufacture activity.
5. Supply activity.

This section provides information on each of the activities and what they cover. A summary table is provided below.

The application process, information required for a medicinal cannabis licence and each activity, and the product assessment process are outlined in more detail in the ***Guideline on the regulation of Medicinal cannabis in New Zealand: Guidance for applicants for a medicinal cannabis licence*** which can be found on our website at: https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms.

Activity	Cultivation	Seed supply	Research	Possession for manufacture	Supply Activity
Activities permitted	• Cultivate medicinal cannabis • Supply: – starting material (as fresh or dried cannabis) to a licence holder with a supply or a possession for manufacture activity – cannabis seeds to a licence holder with a seed supply or cultivation activity – cannabis seed, cuttings, rootstock, tissue for propagation, and tissue culture for export – samples for testing, analysis or non-therapeutic research for export – samples for testing to licence holders with a Licence to deal or Licence to possess controlled drugs or a possession for manufacture activity – Research cultivation (eg. breeding new cultivars). – Receive and possess: – cannabis plants from a cultivation activity licence holder – cannabis seeds imported with a Licence to import controlled drugs – industrial hemp plants and seed from the holder of an industrial hemp licence (limited to 50 seeds and 20 plants).	• Supply medicinal cannabis seed to: – a medicinal cannabis licence holder with a cultivation activity – a person within New Zealand who is authorised to receive it – holders of a Licence to deal or Licence to possess controlled drugs (cannabis seeds) or a possession for manufacture activity. – samples for export for testing, analysis or non-therapeutic research. • Receive and possess: – cannabis seeds from a seed supply or cultivation activity licence holder	• Conduct clinical research • Supply or administer: – a medicinal cannabis product to a person who is a research subject in a clinical trial – samples for testing to a holder of a licence under the Misuse of Drugs Regulations 1977, or a medicinal cannabis licence with a possession for manufacture activity. • Receive and possess: – medicinal cannabis products and cannabis-based ingredients from a supply activity holder for a clinical trial – medicinal cannabis products imported into New Zealand for the purposes of a clinical trial. **Note** – If you are researching cannabis for therapeutic use but which is not part of a clinical trial you may also need one or more of the following licences: • Licence to deal in controlled drugs. • Licence to possess controlled drugs. • Medicinal cannabis licence with a possession for manufacture activity. • Licence to cultivate a prohibited plant.	• Extract fresh or dried starting material to manufacture an initial extract for further processing (considered starting material) • Extract and manufacture a cannabis-based ingredient. • Manufacture a medicinal cannabis product. • Develop medicinal cannabis products. • Conduct testing. • Validate the manufacturing process of a cannabis-based ingredient or a medicinal cannabis product. • Possess and receive: – starting material, cannabis-based ingredients, or medicinal cannabis products from a medicinal cannabis licence holder whose licence authorises its supply – starting material, cannabis-based ingredients, or medicinal cannabis products imported into New Zealand under a Licence to import controlled drugs. **Note** – a medicinal cannabis licence with a supply activity is needed to send samples for testing both within New Zealand and overseas **Note** – to manufacture a medicine for human consumption and for product release testing of these medicines you need a Licence to	• Receive and possess starting material, cannabis-based ingredients, or medicinal cannabis products from: – a medicinal cannabis licence holder whose licence authorises its supply – imported into New Zealand under a Licence to import controlled drugs. • Supply: – starting material for export – cannabis-based ingredients and medicinal cannabis products that have been manufactured in compliance with Good Manufacturing Practice (GMP) for export to countries whose relevant authorities have confirmed their willingness to accept – samples for testing, analysis or non-therapeutic research for export – samples for testing to licence holders with a Licence to deal or Licence to possess controlled drugs or a possession for manufacture activity. – cannabis-based ingredients and medicinal cannabis products that have been verified as meeting the Minimum Quality Standard within New Zealand to: – a medicinal cannabis licence holder with a

Activity	Cultivation	Seed supply	Research	Possession for manufacture	Supply Activity
				manufacture medicines. **Note** – if you are only packaging medicinal cannabis products (eg, over-labelling and secondary packaging) you need a Licence to pack medicines.	research, possession for manufacture, or supply activity – a medicines wholesaler that holds a licence issued under the Misuse of Drugs Regulations 1977 – a holder of a Licence to operate pharmacy – a medical practitioner authorised to receive it under the Medicines Act 1981 **Note** – to manufacture a medicine for human consumption and for product release testing of these medicines you need a Licence to manufacture medicines. **Note** – if you are only packaging medicinal cannabis products (eg, over-labelling and secondary packaging) you may only need a Licence to Pack Medicines.
Other considerations	• **For import of controlled drugs you also need:** – a Licence to import controlled drugs – to meet the Ministry for Primary Industries (MPI) import health standard (phytosanitary requirements) • **For export of controlled drugs you also need:** – a Licence to export controlled drugs.				

3.1 Cultivation Activity

A medicinal cannabis licence with a cultivation activity allows the cultivation of cannabis for use in a medicinal cannabis product.

Cultivation means to grow cannabis plants and undertake physical processes on the plants, such as harvesting, collection, trimming, discarding, and drying[1].

A holder of a medicinal cannabis licence with a cultivation activity may cultivate cannabis to:

- supply starting material to medicinal cannabis licence holders with a supply activity
- supply starting material to a licensed manufacturer of cannabis-based ingredients or medicinal cannabis products
- supply cannabis seeds to another medicinal cannabis licence holder with a seed supply or cultivation activity
- supply cannabis plants to another medicinal cannabis licence holder with a cultivation activity
- supply by export, cannabis seed, cuttings, rootstock, tissue for propagation, and tissue culture (a Licence to export controlled drugs is also required)
- undertake research involving cultivation (for example, research into breeding cultivars with specific characteristics for therapeutic use).

A holder of a medicinal cannabis licence with a cultivation activity may receive and possess:

- cannabis plants from a medicinal cannabis licence holder with a cultivation activity
- cannabis seeds imported into New Zealand under a Licence to Import Controlled Drugs
- industrial hemp plants and seeds from the holder of an industrial hemp licence (limited to 50 seeds and 20 plants from the licence holder)
- cannabis seeds and plants obtained after making a declaration of intent to procure illicit seeds and plants (limited to 50 seeds and 20 plants) of a variety of cannabis that is established in New Zealand (depending on security arrangements).

> **Note**: If you will only be cultivating under your medicinal cannabis licence, you must have an agreement to supply cannabis to the holder of a medicinal cannabis licence with a cultivation, seed supply, possession for manufacture, or supply activity.
>
> If you wish to both cultivate cannabis and manufacture a medicinal cannabis product, you will need to apply for both the cultivation and possession for manufacture activities (and meet other licensing requirements relating to manufacturing).
>
> If you wish to cultivate cannabis to export starting material for commercial therapeutic supply, you will need to apply for both the cultivation and supply activities (and meet other licensing requirements relating to export).

[1] See the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* for more information on Good Manufacturing Practice (GMP) when making dried products

A holder of a medicinal cannabis licence with a cultivation activity may also:

- send samples of their product by export for testing, analysis, or non-therapeutic research only (a Licence to export controlled drugs is also required)
- send samples for testing to a holder of a Licence under the Misuse of Drugs Regulations 1977, or a medicinal cannabis licence with a possess for manufacture activity. The samples must be returned to the cultivation activity holder or destroyed by the testing laboratory (in accordance with licence conditions).

3.1.1 Quality of starting material produced

Starting material intended for either domestic supply or for export is not required to meet the minimum quality standard.

It is the obligation of the cultivator to check what the quality requirements are of the intended receiver of the starting material before applying for a cultivation activity. The requirements may vary, and dictate, for example, the conditions under which the crop is grown, and what pesticides may be used.

3.1.2 Other licences required

A Licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977 is required if you intend to import cannabis seeds, see Section 5: Licences issued under the Misuse of Drugs Regulations 1977. Only cannabis seed may be imported for cultivation at this time due to biosecurity restrictions.

The Ministry for Primary Industries (MPI) applies the biosecurity requirements in relation to the import of seeds under the Biosecurity Act 1993. Under the MPI Plant Biosecurity Index, *Cannabis sativa* seed may be imported, and must meet the specifications of the MPI Import Health Standard – IHS 155.02.05 - Seeds for Sowing.

A possession for manufacture activity, and a Licence to manufacture medicines under the Medicines Act 1981, which includes an assessment of whether you meet the requirements of Good Manufacturing Practice (GMP) are required if you intend to manufacture medicinal cannabis products or cannabis-based ingredients from your cultivated cannabis.

3.2 Seed Supply Activity

A medicinal cannabis licence with a seed supply activity allows the supply of cannabis seeds to another medicinal cannabis licence holder. A seed supply activity is appropriate for a licence holder who intends to act as a 'seed merchant' only.

A holder of a medicinal cannabis licence with a seed supply activity may supply:

- cannabis seeds to a person in New Zealand who is authorised to receive it by any enactment.

A holder of a medicinal cannabis licence with a seed supply activity may receive and possess:

- cannabis seeds from another medicinal cannabis licence holder with a seed supply activity or cultivation activity
- cannabis seed imported into New Zealand under a Licence to Import Controlled Drugs.

A holder of a medicinal cannabis licence with a seed supply activity may not:

- cultivate cannabis plants
- produce cannabis seeds
- possess cannabis plants
- test cannabis seeds.

> **Note**: If you wish to test seeds (eg, for genetic profiling), held under a seed supply activity, samples can be sent to, and tested on your behalf by:
>
> - a holder of a Licence to deal in controlled drugs or a Licence to possess controlled drugs that contains the appropriate authorisation
> - a holder of a medicinal cannabis licence with a possess for manufacture activity.

3.2.1 Other requirements

A Licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977 is required should you wish to import cannabis seed. Authorisation for any importation is consignment specific.

Imported seeds must meet biosecurity requirements under the Ministry for Primary Industries Import Health Standard – *IHS 155.02.05 Seeds for Sowing.* Details of this import health standard can be accessed at: https://www.mpi.govt.nz/import/plants-flowers-seeds-plant-growing-products/seeds-for-sowing/.

3.3 Research Activity

A medicinal cannabis licence with a research activity is required for undertaking clinical trial research investigating cannabis for therapeutic use. Note that a clinical trial or study involving any medicine must be approved by the Director-General of Health. A medicinal cannabis licence with a research activity is required for cannabis and cannabis products that are controlled drugs which are intended to be used as part of the trial. A licence with a research activity may not be required for a product that meets the definition of a CBD product.

A holder of a medicinal cannabis licence with a research activity may receive and possess:

- medicinal cannabis products from a medicinal cannabis licence holder with a supply activity for the purposes of their clinical trial
- medicinal cannabis products imported into New Zealand under a Licence to Import Controlled Drugs for the purposes of their clinical trial.

A holder of a medicinal cannabis licence with a research activity may:

- supply or administer a medicinal cannabis product to a person who is a research subject in their clinical trial or clinical study
- samples for analytical testing to a holder of a Licence to deal in controlled drugs, a Licence to possess controlled drugs that contains the appropriate authorisation, or a medicinal cannabis licence with possession for manufacture activity for testing on your behalf.

The holder of a medicinal cannabis licence with a research activity does not allow:

- the testing of medicinal cannabis products
- non-therapeutic research.

Note, the research activity on a medicinal cannabis licence only enables research for therapeutic purposes. For non-therapeutic research (research not involving a clinical trial or study), one or more of the following licences may be required.

- Licence to possess controlled drugs.
- Medicinal cannabis licence with a possession for manufacturing activity.
- Licence to cultivate a prohibited plant.

3.3.1 Other regulatory requirements

The application and approval process for clinical trials is administered by Medsafe. Ethics approval of a clinical trial by a Health and Disability Ethics Committee is also required. For full guidance on the application and approval process for clinical trials refer to the guidance available on the Medsafe website at: https://www.medsafe.govt.nz/medicines/clinical-trials.asp.

A Licence to manufacture medicines under the Medicines Act 1981 is required for New Zealand manufacturing of cannabis-based ingredients and medicinal cannabis products (including cannabis-derived CBD products) for clinical trials. Products to be administered to humans as part of the trial or study must be manufactured according to Good Manufacturing Practice (GMP). Further information on GMP is available on our website at: https://www.medsafe.govt.nz/regulatory/Guideline/code.asp

3.4 Possession for Manufacture Activity

A medicinal cannabis licence with a possession for manufacture activity is required to produce, manufacture, test and research cannabis starting material, cannabis-based ingredients, and medicinal cannabis products, and engage in process, product or analytical method development.

A holder of a medicinal cannabis licence with a possession for manufacture activity may:

- undertake development of medicinal cannabis products and testing processes related to this development
- extract fresh or dried starting material to create an initial extract for further processing (considered starting material)
- extract and manufacture a cannabis-based ingredient
- manufacture a medicinal cannabis product

- undertake activities related to validating the manufacturing process of a cannabis-based ingredient or a medicinal cannabis product.

A holder of a medicinal cannabis licence with a possession for manufacture activity may possess and receive starting material, cannabis-based ingredients, or medicinal cannabis products:

- from a medicinal cannabis licence holder whose licence authorises its supply
- imported into New Zealand under a Licence to Import Controlled Drugs.

A medicinal cannabis licence with a possession for manufacture activity does not allow:

- supply (including export) of any starting material, cannabis-based ingredients, or medicinal cannabis products.

> **Note:** The possession for manufacture activity does not allow the manufacture of a medicine for human consumption. To do this, a Licence to manufacture medicines issued under the Medicines Act 1981, and compliance with the New Zealand *Code of Good Manufacturing Practice* is required.
>
> For Good Manufacturing Practice queries email GMP@health.govt.nz
>
> Also see *the Guideline on the Regulation of Medicinal Cannabis - Information for New Zealand Manufacturers and Packers of in New Zealand* for more information on the manufacturing and packing process.

3.4.1 Independent laboratory testing on medicinal cannabis

Independent laboratories who wish to undertake testing on medicinal cannabis products and ingredients that are controlled drugs for release testing must hold either a Licence to deal in controlled drugs (Section 5.1) or a Licence to possess controlled drugs (Section 5.2) which authorises them to undertake activities with medicinal cannabis.

In order to perform critical tests (active ingredient and dosage form testing) the laboratory must also be certified as compliant with the New Zealand ***Code of Good Manufacturing Practice***.

For any other tests, you may be either certified as compliant with the New Zealand ***Code of Good Manufacturing Practice*** or be ISO17025:2017 accredited and signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement.

A testing company can continue to perform their testing under their current Licence to deal in controlled drugs (rather than obtaining a medicinal cannabis licence with a possess for manufacture activity) if they are only testing products on behalf of other companies and performing no other activities specific to medicinal cannabis.

Note: Testing does not require a Licence to manufacture medicines.

Medsafe has a program to audit laboratories against the New Zealand code of GMP and issues GMP certificates where appropriate.

For queries relating to GMP certification for release testing email GMP@health.govt.nz

ISO17025:2017 accreditation is issued and audited by International Accreditation New Zealand (IANZ).

For queries relating to ISO17025:2017 accreditation please see the IANZ website: https://www.ianz.govt.nz/.

3.4.2 In-house testing on medicinal cannabis

No additional licences are required to perform product development or release testing if you hold a medicinal cannabis licence with a possession for manufacture activity and a Licence to manufacture medicines.

Note: Where the testing activities require possession of synthetic reference standards a Licence to possess or a Licence to deal in controlled drugs will be required. The Regulations do not allow the importation or possession of synthetic controlled drugs under a medicinal cannabis licence.

3.4.3 Other requirements for manufacture

A Licence to manufacture medicines issued under the Medicines Act 1981 is required to manufacture a medicine for human consumption and for product release testing of these medicines.

A Licence to pack medicines under the Medicines Act 1981 (See Section 4.2) is required if you are only packaging medicinal cannabis products (eg, over-labelling and secondary packaging).

A Licence to import controlled drugs issued under the Misuse of Drugs Regulations 1977 is required if you are importing starting material, cannabis-based ingredients, or medicinal cannabis products.

3.5 Supply Activity

A medicinal cannabis licence with a supply activity is required before you can supply:

- a cannabis-based ingredient
- a medicinal cannabis product (dried product and dosage product)
- consignments of starting material for export.

All products (except for consignments of starting material) that are to be supplied must be specifically named on your medicinal cannabis licence with a supply activity. All medicinal cannabis (including starting material) for export will require a licence to export controlled drugs (see Section 5.5: Licence to export controlled drugs).

If your product needs to meet the minimum quality standard before being listed on your licence, you must apply for a product assessment to verify that the product meets the minimum quality standard (See Section 3.6: Product Assessment). Information on submitting New Medicinal Cannabis Product assessment applications can be found in the *Guidelines on the Regulation of Medicinal Cannabis in New Zealand* which are available on our website at: https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms**.**

> **Note:** A medicinal cannabis licence with a supply activity is not required for the distribution of products that meet the definition of a CBD product. For the supply of a CBD product, you may need a licence under the Medicines Act.
>
> The New Zealand *Code of Good Manufacturing Practice* will need to be met if you are manufacturing cannabis-derived CBD products. You must still apply for a product assessment to verify that the cannabis-derived CBD product meets the minimum quality standard before it can be included on any of the above licences to authorise supply.

A holder of a medicinal cannabis licence with a supply activity may possess:

- starting material, cannabis-based ingredients, or medicinal cannabis products from a holder of a medicinal cannabis licence with a cultivation activity or supply activity
- starting material, cannabis-based ingredients, or medicinal cannabis products that they have grown or manufactured themselves under a cultivation or possession for manufacture activity
- starting material, cannabis-based ingredients, or medicinal cannabis products imported into New Zealand under a Licence to import controlled drugs.

A holder of a medicinal cannabis licence with a supply activity may supply:

- consignments of starting material for export under a Licence to export controlled drugs
- consignments of cannabis-based ingredients or medicinal cannabis products for export which do not meet the minimum quality standard, but have been manufactured in compliance with GMP, and where the importing country accepts the product, with a Licence to export controlled drugs
- consignments of cannabis-based ingredients and medicinal cannabis products for export which do not meet the minimum quality standard, for the purposes of testing, analysis, or non-therapeutic research, with a Licence to export controlled drugs
- cannabis-based ingredients and medicinal cannabis products that meet the minimum quality standard within New Zealand to:
  - a medicinal cannabis licence holder with a research, possession for manufacture, or supply activity
  - a medicines wholesaler that holds a Licence to deal in controlled drugs that contains the appropriate authorisation (See Section 5)
  - a holder of a licence to operate pharmacy issued under the Medicines Act 1981
  - a medical practitioner authorised to receive it under the Medicines Act 1981.

A consignment of starting material, cannabis-based ingredients and medicinal cannabis products that has been specified on a licence may be subject to conditions placed on that product (eg, a product that does not meet the minimum quality standard but has been included on a licence for supply to a

specific holder of a medicinal cannabis licence with a research activity, can only be supplied to that licence holder).

A medicinal cannabis licence with a supply activity does not allow:

- the production or manufacture of any starting material, cannabis-based ingredients, or medicinal cannabis products
- the testing of any starting material, cannabis-based ingredients, and medicinal cannabis products. Samples can be sent to a holder of a Licence to deal in or possess controlled drugs that contains the appropriate authorisation, or the holder of a medicinal cannabis licence with a possession for manufacture activity for testing on your behalf
- the supply of medicinal cannabis products directly to patients.

Situations where a medicinal cannabis licence holder may not require a supply activity include:

- where a holder of a medicinal cannabis licence with a cultivation activity wishes to supply starting material within New Zealand. The licence holder may supply starting material directly to a licensed medicinal cannabis manufacturer without needing to meet the minimum quality standard, and therefore, does not also need to have a supply activity
- where a holder of a medicinal cannabis licence with a cultivation activity wishes to export small samples of starting material for the purpose of analysis, testing or non-therapeutic research. The recipient and the quantity to be exported for these purposes must be listed under the cultivation activity on the medicinal cannabis licence. A Licence to export controlled drugs is still required.

3.5.1 Other licences required

A Licence to import controlled drugs, or a Licence to export controlled drugs issued under the Misuse of Drugs Regulations 1977 is required to import or export starting material, cannabis-based ingredients, or medicinal cannabis products.

3.6 Product assessment

A product assessment is required to verify that the medicinal cannabis product or cannabis-based ingredient intended for supply within New Zealand meets the minimum quality standard. A medicinal cannabis product or cannabis-based ingredient can be named on a medicinal cannabis licence with a supply activity, or a licence issued under the Medicines Act 1981 (for CBD products), after a product assessment has been carried out and it has been verified that the product or cannabis-based ingredient meets the minimum quality standard. More information on submitting a New Medicinal Cannabis Product application can be found in the *Guideline on the Regulation of Medicinal Cannabis in New Zealand - Guidance for a new medicinal cannabis product application*.

Section 4: Licences issued under the Medicines Act 1981

This section outlines the licences issued under the Medicines Act 1981 that may be required for undertaking activities with medicinal cannabis.

The Medicines Act 1981 is administered by Medsafe.

In this section, a licensed manufacturer refers to the holder of a Licence to manufacture medicines under the Medicines Act 1981.

4.1 Licence to Manufacture Medicines under the Medicines Act 1981

Applications for a Licence to manufacture medicines and a licence to pack medicines are to be submitted to the Compliance Management Branch of Medsafe. Please contact GMP@health.govt.nz.

A Licence to manufacture medicines under the Medicines Act 1981 is required for the New Zealand manufacturing of cannabis-based ingredients and medicinal cannabis products (including CBD products) intended for patient use, including for clinical trials. A licensed manufacturer must be able to demonstrate that these products have been made in a GMP compliant facility.

A licensed manufacturer may undertake:

- manufacturing activities, which include product testing, packing and labelling, provided these are within the scope of their Licence to manufacture medicines
- supply of a CBD product.

> For further information on the process for manufacturing medicinal cannabis refer to the *Guideline on the Regulation of Medicinal Cannabis in New Zealand: Guideline for New Zealand Manufacturers and Packers*.
>
> Refer to the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods* and the GRTPNZ Part 4: *Manufacture of Medicines* which can be found on the Medsafe website at: https://www.medsafe.govt.nz/medicines/manufacturing.asp.

A licensed manufacturer may receive and possess:

- initial extracts, cannabis-based ingredients, and medicinal cannabis products that meet the definition of a CBD product.

> For possession of cannabis-based ingredients and medicinal cannabis products that are controlled drugs, see Section 3.4.

Other licences:

A medicinal cannabis licence with a possession for manufacture activity is required when manufacturing a cannabis-derived CBD product from starting material, or manufacturing cannabis-based ingredients, or medicinal cannabis products that are controlled drugs.

4.2 Licence to pack medicines under the Medicines Act 1981

A Licence to pack medicines is required for packaging and/or labelling of medicinal cannabis products (including CBD products) in New Zealand that have been manufactured by a GMP compliant facility. If the licence holder wishes to pack or label medicinal cannabis products that are controlled drugs, then a medicinal cannabis licence with a possession for manufacture activity is also required.

A Licence to manufacture medicines allows for the packing and labelling of medicinal cannabis products, therefore, a licence to pack medicines is not also required.

A Licence to pack medicines is not required when packing medicines manufactured at the same facility as they were produced. A Licence to pack medicines is required for medicines that are manufactured elsewhere.

Applications for a Licence to manufacture medicines and a licence to pack medicines are to be submitted to the Compliance Management Branch of Medsafe. Please contact GMP@health.govt.nz.

A holder of a Licence to pack medicines may (where specified):

- re-package medicinal cannabis products into a secondary container
- label or over-label a medicinal cannabis product
- supply a CBD product where supply is specifically authorised on the Licence to pack medicines.

A holder of a Licence to pack medicines may possess and receive:

- cannabis-based ingredients and medicinal cannabis products (dosage products) that meet the definition of a CBD product (if specified on their licence).

> For possession of cannabis-based ingredients and medicinal cannabis products that are controlled drugs, see Section 3.4.

A Licence to pack medicines does not allow:

- packing or re-packing of a medicinal cannabis product into a primary container. This requires a Licence to manufacture medicines
- the supply of a CBD product that has been packaged or labelled under a licence to pack medicines, unless it is specifically authorised on the licence
- the supply of a medicinal cannabis product that is a controlled drug.

> **Note:** A new medicinal cannabis product (NMCP) application is required to supply a medicinal cannabis product that has been packaged or labelled under a Licence to pack medicines. The process for applying for a product assessment is included in the *Guideline on the Regulation of Medicinal Cannabis in New Zealand - Guidance for a New Medicinal Cannabis Product Application*.

Other licences:

A medicinal cannabis licence with a possession for manufacture activity is required for packing of medicinal cannabis products that are controlled drugs.

A medicinal cannabis licence with a supply activity is required for supply of medicinal cannabis products that are controlled drugs.

4.3 Good Manufacturing Practice certification

GMP certification is not required for the development of a medicinal cannabis product or ingredient. The medicinal cannabis product or ingredient must be developed before it can meet GMP. During product development, testing conducted under the ISO/IEC 17025 Testing and Calibration Laboratories Accreditation is suitable.

Good Manufacturing Practice (GMP) certification is required for the manufacturing, product release testing and packing site of each consignment of cannabis-based ingredient, and medicinal cannabis product before they can be supplied for human consumption in New Zealand. This applies to both imported products and products manufactured in New Zealand.

For further guidance on GMP, see:

- the New Zealand Code of Good Manufacturing Practice
- the Guideline on the Regulation of Medicinal Cannabis in New Zealand: Guidance for manufacturers and Packers
- the Guidelines on the Regulation of Therapeutic Products in New Zealand (GRTPNZ) Part 4: Manufacture of Medicines
- the Medsafe Schedule of Fees for fees relating to GMP certification.

These can all be found on the Medsafe website at: https://www.medsafe.govt.nz/medicines/manufacturing.asp and the Medicinal Cannabis Agency website at https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms.

The Medsafe Compliance Management Branch has a process to certify overseas medicine manufacturing sites under GMP. If you would like to know more about the overseas GMP certification process, please contact GMP@health.govt.nz.

4.4 Licence to Sell Medicines by Wholesale under the Medicines Act 1981

A Licence to sell medicines by wholesale is required to import and supply a CBD product in New Zealand.

Applications for a Licence to sell medicines by wholesale, or to amend an existing Licence to sell medicines by wholesale are to be submitted to the Medicines Control branch of Medsafe. For further information on the application process contact medicinescontrol@health.govt.nz

A cannabis-derived CBD product can only be supplied in New Zealand with a Licence to sell medicines by wholesale if it is verified against the minimum quality standard and must be expressly authorised (named) for supply on that licence.

A non-cannabis derived CBD product is unable to be assessed against, nor is it required to meet, the minimum quality standard. Rather these can be authorised for supply on a Licence to sell medicines by wholesale with no product assessment.

A holder of a Licence to sell medicines by wholesale may procure, possess and supply:

- a CBD product that is specifically authorised for supply by the Licence to sell medicines by wholesale (by import or from an appropriate licence holder).

> **Note:** If you wish to use a Licence to sell medicines by wholesale to distribute a cannabis-derived CBD product that is verified as meeting the minimum quality standard under another supplier's licence, you must apply to Medicines Control for an amendment to have the cannabis-derived CBD product named on your licence. A new product assessment is not required if evidence is provided of a commercial agreement with the licence holder who has had the product assessed and verified as meeting the minimum quality standard.

Section 5: Licences issued under the Misuse of Drugs Regulations 1977

This section describes the activities that may be undertaken with a Licence to deal, possess, import, and export controlled drugs, and cultivate a prohibited plant. The activities outlined below are in relation to medicinal cannabis that is a controlled drug only.

Applications for licences issued under the Misuse of Drugs Regulations 1977 are to be submitted to Medicines Control. For further information on the application process contact medicinescontrol@health.govt.nz

Note: Licences issued under the Misuse of Drugs Regulations 1977 are not required for ingredients and products that meet the definition of a CBD product. However, requirements under the Medicines Act 1981 and Medicines Regulations 1984 may apply.

5.1 Licence to Deal in Controlled Drugs

A Licence to deal in controlled drugs must specify the particular substance(s) it applies to (note this may be by class or group of controlled drugs or be product specific) in order for the activities below to be applicable.

Applications for a Licence to deal in controlled drugs are to be submitted to Medicines Control. For further information on the application process, contact medicinescontrol@health.govt.nz

A holder of a Licence to deal in controlled drugs may, where authorised by the licence:

- undertake the testing of cannabis, including starting material, cannabis-based ingredients, and medicinal cannabis products (for testing facilities whose only business with medicinal cannabis products is to test them on another company's behalf)
- possess and use synthetic reference standards
- research cannabis, obtained by import or from a holder of a licence to cultivate a prohibited plant, for non-therapeutic purposes
- distribute a medicinal cannabis product that has been verified as meeting the minimum quality standard and named on a separate medicinal cannabis licence with a supply activity. This means that a wholesaler/distributer who is only sourcing medicinal cannabis products that meet the minimum quality standard from licensed suppliers, can continue to operate under a Licence to deal in controlled drugs.

Note: If you wish to use a Licence to deal in controlled drugs to distribute a medicinal cannabis product that has been verified as meeting the minimum quality standard, then you must apply to have the particular medicinal cannabis product named on your licence. A product assessment is not required if evidence is provided of a commercial agreement with the medicinal cannabis licence holder who has had the product assessed.

5.2 Licence to possess controlled drugs

A Licence to possess controlled drugs must specify particular substance(s) it applies to (note this may be by class or group of controlled drugs, or product specific) in order for the below activities to be applicable.

Applications for a Licence to possess controlled drugs are to be submitted to Medicines Control. For further information on the application process, contact medicinescontrol@health.govt.nz

A holder of a Licence to possess controlled drugs may, where authorised by the licence:

- undertake the testing of cannabis, including starting material, cannabis-based ingredients, and medicinal cannabis products (for testing facilities whose only business with medicinal cannabis products is to test them on another company's behalf)
- possess and use synthetic reference standards.

A Licence to possess controlled drugs does not allow:

- the licence holder to supply any cannabis to be tested, including starting material, cannabis-based ingredients, and medicinal cannabis products, to any other party, including the company they are testing on behalf of. Therefore, test samples must be destroyed when no longer in use.

5.3 Licence to Import Controlled Drugs

A Licence to import controlled drugs is required for the importation of controlled drugs, including starting material, cannabis-based ingredients, medicinal cannabis products and cannabis seed. Licensing is consignment specific and up to four different starting materials/cannabis-based ingredients/medicinal cannabis products/cannabis seeds can be specified per application.

A Licence to import controlled drugs is only issued if the importer holds a relevant licence allowing them to obtain and possess the cannabis, starting material, cannabis-based ingredient, or medicinal cannabis product.

Note: A Licence to import controlled drugs is also required to import other controlled drugs, such as synthetic reference standards.

You may apply for a Licence to import controlled drugs for starting material, cannabis-based ingredient, medicinal cannabis product, or cannabis seed. To apply for a Licence to import controlled drugs, contact Medicines Control at medicinescontrol@health.govt.nz**.** Note that licences to import are only valid for a specified amount of time.

> **Note:** The Ministry for Primary Industries (MPI) applies the biosecurity requirements in relation to the import of seeds and plant material under the Biosecurity Act 1993. The seeds for sowing and species approved for import are listed on the MPI Plants Biosecurity Index. Under the MPI Plant Biosecurity Index, *Cannabis sativa* seed may be imported, as per the import specifications of the MPI Import Health Standard – IHS 155.02.05 Seeds for Sowing. You cannot import plant material (nursery stock) from overseas sources until a Plant Import Health Standard for cannabis has been issued by the Ministry for Primary Industries.

5.4 Licence to export controlled drugs

A Licence to export controlled drugs is required for the export of controlled drugs, including starting material, cannabis-based ingredients, and medicinal cannabis product or seed. Licensing is consignment specific and up to four different starting materials/cannabis-based ingredients/medicinal cannabis products can be specified per application.

A Licence to export controlled drugs is only issued if the exporter holds a medicinal cannabis licence with an appropriate activity. Prior to export, the exporter must hold a medicinal cannabis licence with a supply activity that names the specific product they wish to export. To apply for a Licence to export controlled drugs, contact Medicines Control at: medicinescontrol@health.govt.nz**.**

> **Note:** Authorisation of import must be provided by a relevant authority of the importing country before a Licence to export controlled drugs can be issued.

Section 6: Licences issued under the Misuse of Drugs (Industrial Hemp) Regulations 2006

6.1 General or Research and breeding licences

Industrial hemp licences are granted for the cultivation of hemp for industrial (non-medicinal) purposes. Holders of only an industrial hemp licence cannot carry out any activities that require a medicinal cannabis licence.

Holders of a general or research and breeding industrial hemp licence can supply no more than 50 seeds and 20 plants of industrial hemp from an industrial hemp licence holder to the holder of a medicinal cannabis licence with a cultivation activity.

Information on industrial hemp licensing can be found on the Ministry of Health website at https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/industrial-hemp**.**