

GUIDELINE ON THE REGULATION OF MEDICINAL CANNABIS IN NEW ZEALAND

Key changes to the Medicinal Cannabis Scheme July 2024

Citation: Ministry of Health. 2024. *Guideline on the regulation of medicinal cannabis in New Zealand: Key changes to the Medicinal Cannabis Scheme July 2024*. Wellington: Ministry of Health.

Published in July 2024 by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

HP 9079



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Section 1: Introduction

This document is intended to help current or potential licence holders understand the key changes to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) and provides guidance on how to comply with the new requirements. These changes will take effect from 05 July 2024.

We recommend also reading the updated ***Guidelines on the regulation of medicinal cannabis in New Zealand*** in full. These have been updated to reflect the changes outlined in this document. These guidelines can be found on our website at: <https://www.health.govt.nz/publication/medicinal-cannabis-scheme-guideline-and-forms>.

While we have made every effort to explain the key changes to the Regulations, it is the licence holders' responsibility to understand their obligations under the Misuse of Drugs Act 1975 (the Act), the Regulations, and any other legislation when working under the Medicinal Cannabis Scheme (the Scheme).

The Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (the Amendment Regulations) can be read in full on the New Zealand legislation website at: <https://www.legislation.govt.nz/regulation/public/2019/0321/latest/LMS285243.html>.

If you have any questions regarding the changes, please contact us at medicinalcannabis@health.govt.nz.

1.1 Overview of the changes to the Regulations

Changes have been made to the Regulations which may affect you. These include:

- changes to export settings, including:
 - export of starting material
 - export of cannabis-based ingredients and medicinal cannabis products
 - export of CBD ingredients and products
 - export of medicinal cannabis seed
 - export of medicinal cannabis for testing, analysis, or non-therapeutic research purposes
- changes to licensing
 - redefining the scope of the 'nursery' activity to 'seed supply'
- changes to the minimum quality standard, including:
 - changes to permitted tests and required testing
 - changes to requirements for laboratories
 - changes to pesticide requirements

Please familiarise yourself with the changes outlined in this document. We have outlined changes to the current processes or requirements, and what these changes may mean for you.

Section 2: Changes to export settings

From 05 July 2024, there will be changes to export settings for medicinal cannabis. The details of these changes are outlined in this section.

2.1 Export of starting material

From 05 July 2024, consignments of starting material will no longer need to be verified as meeting the minimum quality standard before export.

The definition of starting material will be widened to include initial extracts from cannabis plant material which are intended to undergo further processing or extraction into a cannabis-based ingredient.

A medicinal cannabis licence with a supply activity will still be required to export starting material, however, consignments are no longer required to be individually listed on the licence. The licence will instead have a condition on the supply activity permitting the export of any starting material.

A licence to export controlled drugs under the Misuse of Drugs Regulations 1977 is still required for each shipment of starting material which is a controlled drug. Information on applying for a licence to export can be found on the Medicines Control pages of the Ministry of Health website at: <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control>.

There will be a general condition on all medicinal cannabis licences with a possession for manufacture activity regarding initial extracts which meet the definition of a CBD product under [Section 2A of the Misuse of Drugs Act 1975](#). The licence holder must demonstrate to the Agency that the initial extract meets the definition by providing a certificate of analysis.

Where the starting material exported is a controlled drug, you will need to provide a monthly return report and submit this to the Agency.

2.2 Export of cannabis-based ingredients and medicinal cannabis products

From 05 July 2024, verification against the minimum quality standard (MQS) will not be required for exports of cannabis-based ingredients (CBIs) and medicinal cannabis products that are:

- intended for the overseas market only
- manufactured under Good Manufacturing Practice (GMP)
- accepted by the importing country.

Domestically manufactured CBIs and medicinal cannabis products which have been verified as meeting the MQS will continue to be able to be exported.

To produce a CBI or medicinal cannabis product for export the CBI or product must be manufactured by the holder of a licence to manufacture medicines, whose licence authorises the manufacture of that CBI or medicinal cannabis product.

The unverified CBI or medicinal cannabis product for export must have a unique tradename or identifier which is distinct from any ingredient or product that has been verified as meeting the MQS.

Prior to exporting a CBI or medicinal cannabis product which has not been verified against the MQS you will also need to ensure that:

- the CBI or medicinal cannabis product is listed on your medicinal cannabis licence under the supply activity (an amendment to the medicinal cannabis licence will be required each time additions are made)
- you provide evidence to Medicines Control that the importing country is willing to accept the goods (eg, a copy of an import licence issued by the overseas authority or letter from the relevant regulatory authority).

Once listed on your medicinal cannabis licence with a supply activity, you will still require a licence to export controlled drugs for each shipment. It is important to ensure that the name of the ingredient or product on your licence to export controlled drugs application must match the details on your medicinal cannabis licence with a supply activity.

The export of all controlled drugs including unverified CBIs and medicinal cannabis products must be included on the monthly return report.

CBIs and products that are intended for export only cannot be supplied within New Zealand.

The MQS will apply to imported CBIs and medicinal cannabis products for supply through the New Zealand supply chain. Therefore, consignments of unverified medicinal cannabis products cannot be re-imported back into New Zealand.

2.3 Export of CBD ingredients and CBD products

From 05 July 2024, verification against the minimum quality standard (MQS) will no longer be required for exports of cannabis-derived CBD products¹ (as ingredients or final products) that are:

- intended for the overseas market only
- manufactured under GMP
- accepted by the importing country.

Domestically manufactured CBD products that have been verified as meeting the MQS will continue to be able to be exported.

To produce a CBD product (ingredient or final product) for export it must be manufactured by the holder of a licence to manufacture medicines, whose licence authorises the manufacture of that CBD product (as an ingredient or final product).

¹ As defined in section 2A of the Misuse of Drugs Act 1975

The unverified CBD product (ingredient or final product) for export must have a unique tradename or identifier which is distinct from any ingredient or product that has been verified as meeting the MQS.

To have the product listed, the manufacturer will need to supply the following to the Compliance branch of Medsafe and the Medicinal Cannabis Agency:

- a certificate of analysis (CoA) to demonstrate that the CBD product (ingredient or final product) meets the definition of a CBD product
- evidence to demonstrate that the importing country accepts the products (eg, a letter from the relevant regulatory authority).

The MQS requirements will apply to imported CBD products for supply through the New Zealand supply chain. Therefore, consignments of unverified CBD products cannot be re-imported into New Zealand by a medicinal cannabis licence holder.

2.4 Export of medicinal cannabis seed, cuttings, rootstock, tissue, and tissue culture

A medicinal cannabis licence with a seed supply activity will now permit the export of medicinal cannabis seed. A separate licence to deal in controlled drugs will no longer be required.

A medicinal cannabis licence with a cultivation activity will now permit the export of medicinal cannabis seed, cuttings, rootstock, tissue, and tissue culture for propagation. It is important to note that the cultivation activity only allows the export of cannabis for propagation. Where the supply of these materials is for commercial therapeutic purposes a supply activity is required for export. A separate licence to deal in controlled drugs will no longer be required.

A licence to export controlled drugs, will still be required for every shipment. Information on applying for a licence to export can be found on the Medicines Control pages of the Ministry of Health website at: <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control>.

The export of all controlled drugs including seed, cuttings, rootstock, tissue, and tissue culture, must be included on the monthly return report to the Agency.

The holding of a licence to enable this activity does not guarantee that the export of this material can occur. It is the exporter's responsibility to ensure that all other relevant requirements are met, such as biosecurity and phytosanitary requirements. Should you have any questions regarding requirements outside of the Scheme the relevant agency should be contacted.

2.5 Export of medicinal cannabis for testing, analysis, or non-therapeutic purposes

From 05 July 2024, samples of medicinal cannabis that are being exported for testing, analysis, or non-therapeutic purposes will not have to meet the minimum quality standard (MQS). The medicinal cannabis being exported must:

- be listed as permitted for export for testing, analysis, or non-therapeutic purposes only on the medicinal cannabis licence (with a supply or cultivation activity) of the exporter (an amendment to the medicinal cannabis licence will be required each time additions are made)
- be in an amount justified by the licence holder which is acceptable to the Agency as necessary for export for testing, analysis, or non-therapeutic purposes.

For samples which are controlled drugs, a licence to export controlled drugs, will still be required for every shipment. Information on applying for a licence to export can be found on the Medicines Control pages of the Ministry of Health website at: <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control>.

It is the exporter's responsibility to ensure that any other requirements, such as biosecurity and phytosanitary requirements, are met. Should you have any questions regarding requirements outside of the Scheme the relevant agency should be contacted.

Section 3: Changes to Licensing

From 05 July 2024, minor changes to the licence activities will be made. Including, the scope of the 'nursery' activity which will be redefined to 'seed supply' and stocktake requirements will also be clarified.

Cultivars of medicinal cannabis will no longer be listed individually on the 'cultivation' activity of the licence except where a location is authorised for the cultivation of low THC cannabis.

3.1 Re-defining the scope of the 'nursery' activity to 'seed supply'

From 05 July 2024, the 'nursery' activity will be renamed 'seed supply'. This change is to reflect the activities that are permitted to be carried out under this activity.

Activities relating to the cannabis plant (procurement, possession, cultivation, and supply) will no longer be permitted under a 'seed supply' activity as these activities are already more appropriately authorised under a cultivation activity.

This change will have no tangible impact on existing licences. To date, any activities relating to cannabis plant have been enabled under a cultivation activity.

If you currently hold a medicinal cannabis licence with a 'nursery' activity – you do not need to take immediate action.

The 'nursery' activity on your licence will be updated to 'seed supply' when you next apply for a medicinal cannabis licence renewal or amendment. The transition provisions in the Amendment Regulations enable licence holders who currently hold a licence with a nursery activity and wish to export seeds to do so under their existing licence.

3.2 Records of stocktake for any activity

From 05 July 2024, regulation 67 of the Regulations will be updated to clarify that "end of any year" means 31 December of any year.

Medicinal cannabis licence holders will be required to provide the Medicinal Cannabis Agency with these records and account by 31 January of the following year.

From 05 July 2024, regulations 63 to 66 of the Regulations will be updated to clarify that medicinal cannabis licence holders must also keep records of any cannabis, starting material, cannabis-based ingredients or medicinal cannabis products that are destroyed by the licence holder.

3.3 Listing of cultivars on the licence

From 05 July 2024, a licence with a cultivation activity will no longer list cultivars individually where a location is authorised to grow high THC cannabis. Instead, the cultivation activity will state “All cannabis cultivars”. This means that licence holders will no longer have to apply to amend the licence when they want to change cultivars.

For locations that are authorised only for low THC cannabis cultivation, the licence will continue to list the low THC cannabis cultivars by name and THC content. Licence holders will need to apply to amend the licence if they wish to change to other low THC cannabis cultivars or if they wish to grow high THC cannabis cultivars. In the latter situation, an assessment of the security arrangements will be required.

Section 4: Changes to the minimum quality standard

From 05 July 2024, changes to the minimum quality standard (MQS) will be made. This includes:

- allowing dried cannabis to be used as an ingredient in products
- changes to permitted tests and required testing
- changes to requirements for laboratories
- changes to pesticide requirements.

These changes allow more flexibility in the required test methods, where the testing is completed, and at which stage these tests must be completed. The changes also remove duplicate testing where appropriate. Changes to the pesticide requirements have been made to allow for the use of a broader range of pesticides.

4.1 Dried cannabis as an ingredient in products

Dried cannabis, when used as a cannabis-based ingredient (CBI) in products (eg, capsules) intended for domestic supply must comply with the minimum quality standard (MQS).

Where dried cannabis is used as a CBI in products, the required testing of a CBI, as well as testing for foreign matter, loss on drying, and total ash will be required.

4.2 Changes to permitted tests and required testing

From 05 July 2024, a number of changes are being made to the tests and where testing is required. The changes are outlined in the following sections below.

4.3 Changes to the testing requirements

From 05 July 2024, dosage products being verified as meeting the minimum quality standard (MQS) can have the following tests conducted in **either** the cannabis-based ingredient (CBI) or the final dosage product:

- heavy metals
- pesticides
- absence of aflatoxins
- ochratoxin A
- residual solvents.

If the above testing is only being conducted on the cannabis-based ingredient, then evidence to demonstrate that the final dosage product will not exceed the maximum limits for these specifications will need to be provided as part of the product assessment application.

For example, evidence could be provided to demonstrate that to produce the final product, the sole manufacturing step is dilution of the CBI with an excipient which does not contain any heavy metals. Therefore, testing for heavy metals would not also be required in the final product.

If the above testing is only being conducted in the final dosage product, a product assessment application for the CBI still needs to be provided for assessment of other parameters such as stability. However, the CBI will not be verified by the Agency as meeting the MQS unless the full set of testing requirements under the Regulations are met.

The medicinal cannabis will also need to be tested as applicable to the category of product (eg, dried product, CBI for sale, final product). Please see Table 1 below for an overview of the updated testing requirements.

Table 1: Testing requirements for medicinal cannabis to meet the minimum quality standard

Applicable test	Test in dried product	Test in dried CBI	Test in CBI	Test in CBI not for supply	Final dosage product
Identification of Cannabis (microscopic and macroscopic)	✓	✓	✓	✓	✓
Identification of active ingredients	✓	✓	✓	✓	✓
Microbiological contamination	✓	✓	✓	✓	✓
Heavy Metals	✓	✓	✓	✓ *	✓ *
Pesticides ■	✓	✓	✓	✓ *	✓ *
Absence of Aflatoxins	✓	✓	✓	✓ *	✓ *
Ochratoxin A	✓	✓	✓	✓ *	✓ *
Foreign Matter	✓	✓			
Loss on drying	✓	✓			
Total ash	✓	✓			
Residual solvents ▲	✓ ▲	✓ ▲	✓ ▲	✓ *▲	✓ *▲

* These may be tested in either the final dosage product only, or in the CBI only, if can be demonstrated that there is no risk that the final dosage product exceeds the test limits specified.

▲ You may not need to test for residual solvents if you can demonstrate that there is no risk of their presence (for instance if you are producing dried cannabis, and solvents are not used during manufacture).

■ Note, there are different pesticide testing requirements for imported medicinal cannabis compared to New Zealand grown cannabis. For further details, see the *Guideline on the regulation of medicinal cannabis in New Zealand: Pesticide use on medicinal cannabis crops*.

4.3.1 Changes to the permitted tests

From 05 July 2024, you will be able to use a wider range of permitted tests. Please note that while the Medicinal Cannabis Agency will now accept a wider range of tests, the maximum limits will remain consistent.

The following alternative test methods from the *United States Pharmacopoeia – National Formulary (2023 issue 1)* will be accepted:

- heavy metals (USP <561>)
- pesticides (USP <561>)
- absence of aflatoxins (USP <561>)
- loss on drying (USP <731>)
- total ash (USP <561>)
- residual solvents (USP <467>).

The following alternative test method from the *British Pharmacopoeia 2023* will be accepted:

- total ash (BP Appendix XI.J).

Please note that many test methods in the *British Pharmacopoeia 2023* are harmonised with the *European Pharmacopoeia (11th edition, version 11.0 of the European Pharmacopoeia, including supplement 11.3)* and are considered equivalent.

4.3.2 Changes to permitted excipients

From 05 July 2024, in addition to the *European Pharmacopoeia*, you will be permitted to use excipients with monographs in the following pharmacopoeia:

- the *British Pharmacopoeia 2023*
- the *United States Pharmacopoeia – National Formulary (2023 issue 1)*.

4.3.3 Changes to assay limits of active ingredients

From 05 July 2024, the requirements for assay limits will change in the following ways:

- for cannabis-based ingredients (CBIs), manufacturers will be able to set their own assay limits, these must be set in compliance with GMP
- for medicinal cannabis products, a ‘less than’ limit may be applied when an active ingredient (meaning THC, THCA, CBD, and CBDA) in a medicinal cannabis product is present at very low levels and difficult to control within the specified range.

For cannabis-based ingredients (CBIs) where the manufacturer has specified assay limits, you will need to demonstrate that the active ingredient present is within the range specified.

For medicinal cannabis products, you will need to demonstrate that the level of the active ingredient is low and difficult to control within the specified range for a ‘less than’ limit to be applied. Examples of levels that are considered low levels, where a less than limit may be appropriate, include the following:

- oral liquids – where the active ingredient is less than 2 mg/mL
- dried cannabis flower (flower for inhalation or tea)– where the active ingredient is less than 10 mg/g or 1% w/w.

The Agency will not verify medicinal cannabis products where all active ingredients are assayed at a 'less than' limit specified by the manufacturer. The Agency will also consider the differences between active ingredient concentrations when determining if a 'less than' assay limit is justifiable.

4.3.4 Changes to container material requirements

From 05 July 2024, container material may comply with any of the following:

- *European pharmacopoeia* Chapters 3.1 and 3.2
- *United States Pharmacopoeia – National Formulary (2023 issue 1)* Chapters <660>, <661.1>, or <661.2>
- *European Medicines Agency Guideline on Plastic Immediate Packaging Materials*.

If food grade plastic packaging is being used in accordance with the *European Medicines Agency Guideline on Plastic Immediate Packaging Materials*, the materials will need to be appropriately certified. Examples of appropriate certification includes, but is not limited to, the following:

- certification demonstrating compliance with EC 2023/2006 and EC 10/2011
- certification demonstrating compliance with US FDA 21 CFR Part 177 and US FDA 21 CFR 176.170.

4.4 Changes to requirements for laboratories

From 05 July 2024, non-critical tests will be able to be carried out by either GMP certified manufacturers, or laboratories with GMP accreditation or ISO/IEC 17025:2017 accreditation. This means that GMP certification will only be mandatory for the following testing (critical tests).

- Assay limits for active ingredients.
- Dosage form requirements.

ISO/IEC 17025:2017 accreditation or GMP certification will be accepted for the following testing:

- microbiological contamination
- heavy metals
- pesticides
- absence of aflatoxins
- ochratoxin A
- foreign matter
- loss on drying
- total ash
- residual solvents.

ISO 17025:2017 accredited laboratories will need to be signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement.

Testing of container material will be exempted from being carried out by a GMP-certified manufacturer or laboratory. See the Guideline on the regulation of medicinal cannabis in New Zealand – Guidance for a New Medicinal Cannabis Product application.

4.5 Changes to pesticide requirements

From 05 July 2024, the pesticides permitted for use on medicinal cannabis will be expanded. There will be different requirements for:

- medicinal cannabis to be used in inhalation products
- medicinal cannabis to be used in non-inhalation products.

An overview of the new requirements can be seen in the following table.

Table 2: Guidance on allowable pesticide use on medicinal cannabis under the minimum quality standard.

Pesticide requirement that applies to meet the minimum quality standard	Medicinal cannabis for inhalation products	Medicinal cannabis for non-inhalation products
Pesticide use must be permitted in the country that the medicinal cannabis is grown.	✓	✓
Pesticide products specifically authorised for use on medicinal cannabis may be used. Details of the assessment authorising use must be provided and label conditions must be followed.	✓	✓
Pesticides with active ingredients listed in the Regulations may be used.	✓	✓
Pesticides with active ingredients listed in Schedule 2 of the Food Notice: Maximum Residue Levels for Agricultural Compounds may be used		✓
Pesticide active ingredients in Agricultural Compounds and Veterinary Medicines Act 1997 registered products, that are allowed for use on food, and may be used (as off label use). Pesticide products used in New Zealand must be registered products. Pesticide products used overseas must be permitted for use on foods in the country of use.		✓
Residues in Regulation 7 must be tested for.	✓	✓
Residues of any pesticides that may be used which are not on this list or in Schedule 2 of the Food Notice: Maximum Residue Levels for Agricultural Compounds must be tested for		✓

Whilst we have provided a summary of the changes to pesticide requirements above, the changes to pesticide requirements have been outlined in full in the **Guideline on the regulation of medicinal cannabis in New Zealand: Pesticide use on medicinal cannabis**, and it is highly recommended that you refer to the full Guideline.