MEDICINAL CANNABIS AGENCY

MINISTRY OF HEALTH
MANATŪ HAUORA

GUIDELINE ON THE REGULATION OF MEDICINAL CANNABIS IN NEW ZEALAND

PART 5

Guidance for a Changed Medicinal Cannabis Product Application

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Section 1: Introduction

Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) sets the minimum quality standard requirements for medicinal cannabis products and ingredients. A medicinal cannabis product or ingredient that has been verified as meeting the minimum quality standard (the Quality Standard) can be lawfully supplied in New Zealand, subject to the appropriate licence. A medicinal cannabis product or ingredient that has been verified as meeting the Quality Standard can be added to a Medicinal Cannabis Licence with a Supply activity, or to a licence issued under the Medicines Act 1981 (for cannabidiol (CBD) products).

A Changed Medicinal Cannabis Product (CMCP) application is required for any verified medicinal cannabis product or cannabis-based ingredient listed on a current Medicinal Cannabis Licence with Supply activity or licence issued under the Medicines Act 1981 that is affected by a change to any of the matters listed in regulation 47(1)(e) of the Regulations. The application should provide sufficient evidence to satisfy the Medicinal Cannabis Agency (the Agency) that the product or ingredient continues to meet the Quality Standard.

You must make a CMCP application when a product or ingredient has a proposed change to:

- its trade name
- the label or description that will accompany it
- its composition, or its formulation (ie, the ingredients or the quantity or proportion of each ingredient)
- its method of manufacture (including packing and testing)
- its container closure system (including packaging material)
- the facilities for its manufacture (including packing and testing facilities)
- the recommended method of administering, applying or using it
- its shelf life or storage conditions.

You cannot change any of the above matters without the approval of the Agency. Verification of the changes must be completed before you distribute any batches affected by the change(s). In your application, you must include sufficient evidence to demonstrate that the product or ingredient will continue to meet the Quality Standard after the change.

Once the Agency is satisfied that the proposed change to the medicinal cannabis product or cannabis-based ingredient meets the Quality Standard, the Agency will make a recommendation that the product can continue to be supplied under the applicant's licence with the proposed changes. Any amendments required to your Medicinal Cannabis licence will be included in the recommendation. Any amendments required to a Medicines Act 1981 licence will need a separate amendment application in order to amend your licence.

This document is **Part 5: Guidance for a Changed Medicinal Cannabis Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand.* It outlines how to make an application for a planned change to a medicinal cannabis product.

Note: If your product has not been verified by the Agency as meeting the Quality Standard, a New Medicinal Cannabis Product (NMCP) application will be required. For more information on NMCP applications, see Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand.

The CMCP process does not apply to starting material for export. The assessment of a starting material for export will always involve an NMCP application because each consignment of starting material for export must be assessed before it can be exported.

1.1 Structure of this guideline

Section 1 (this section) provides the context for a CMCP application and the types of changes that require an assessment. It includes regulatory references and additional information that will help you complete an application.

Section 2 introduces and identifies the change categories and how they apply to different proposed changes to a cannabis-based ingredient or medicinal cannabis product. This section also covers the evidence you must include in your application to demonstrate that the planned change to a cannabis-based ingredient or medicinal cannabis product continues to meet the Quality Standard.

Section 3 is a guide to preparing a CMCP application for a planned change to a cannabis-based ingredient or a medicinal cannabis product that has previously been verified as meeting the quality standards.

This section follows the same format as the CMCP application form. For the application form, go to the Agency's website.

1.2 Legislation relating to the Quality Standard requirements

The following legislation relates to the requirements of the Quality Standard:

- Misuse of Drugs (Medicinal Cannabis) Regulations 2019
- Misuse of Drugs Act 1975
- Misuse of Drugs Regulations 1977
- Medicines Act 1981
- Medicines Regulations 1984.

1.3 Other information relevant to this guideline

The following information will help you to conform to the Quality Standard:

- European Pharmacopoeia (Ph Eur) 10th edition
  - General monograph Pharmaceutical Preparations (2619)

- International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH) quality guidelines:
  - Q1A(R2) Stability Testing of New Drug Substances and Products
  - Q2(R1) Validation of Analytical Procedures: Text and Methodology
- New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods
- ISO/IEC 17025 Testing and Calibration Laboratories Accreditation
- World Health Organization (WHO) Model Certificate of Analysis.

Section 2: Proposed changes

This section provides guidance on the information that is required for a CMCP application form along with supporting documents for proposed changes to be made to the cannabis-based ingredient or medicinal cannabis product.

The tables in section 2.1 (for cannabis-based ingredient) and 2.2 (for medicinal cannabis products) describe:

- proposed changes
- the regulations that apply to those changes
- the documentation required in an application for the proposed change
- the "change category".

The Change category is a number from 1 to 3 that represents how complex the change is and therefore which fee will relate to that change. Change categories are described in the table below.

The application fee is GST exclusive.

A tax invoice for the CMCP fee will be sent to the licence holder's contact person; the licence holder being the entity legally responsible for the application.

At the applicant's request, the Agency will include a customer reference to the invoice.

Change category	Complexity of change	Fee (excluding GST)
1	Low	$660
2	Medium	$1,200
3	High	$2,100

If you have multiple changes, a fee for each change will be charged and you will be invoiced for the combined total, noting that the total fee will not exceed the fee for a new medicinal cannabis product application.

You will need to identify which changes in the tables below apply to the proposed change(s) to your cannabis-based ingredient or medicinal cannabis product before submitting your CMCP application.

2.1 Proposed cannabis-based ingredient changes

2.1.1 Cannabis-based ingredient trade name

Cannabis-based ingredient trade name	Regulation	Documentation required	Change category
New product name to replace existing name	47(1)(e)(i)	1	1
Documentation			

Proposed new trade name (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for trade name requirements).

2.1.2 Cannabis-based ingredient composition

Cannabis-based ingredient composition	Regulation	Documentation required	Change category
Minor change in the composition of an active ingredient or ingredient that does not affect stability	47(1)(e)(iii)	1, 2, 3, 4, 5, 6	2
Documentation			
1 Revised formulation table.			
2 Certificates of analysis for three representative batches of the revised formulation. Batches should be at least pilot scale manufactured using full production scale equipment.			
3 If applicable: Amended batch manufacturing description (must not be a significant manufacturing change which should be completed as per 2.1.3).			
4 If applicable: Revised specifications/test methods for the cannabis-based ingredient (refer to 2.1.4).			
5 If applicable: Revised specifications/test methods for the medicinal cannabis product (refer to 2.2.5).			
6 If applicable: Revised label for the medicinal cannabis product (refer to 2.2.2).			

2.1.3 Cannabis-based ingredient manufacturing site and process

Cannabis-based ingredient manufacturing site/process	Regulation	Documentation required	Change category
Change in ownership or site name of manufacturing site for cannabis-based ingredient	47(1)(e)(vi)	1	1
Change in the commercial batch size (more than 10-fold the size of the original batches submitted for verification)	47(1)(e)(iv)	3 (if previous submitted batch sizes are no longer representative), 4	1
New site of manufacture for cannabis-based ingredient	47(1)(e)(vi)	2, 3, 6	2
New/revised manufacturing process for cannabis-based ingredient	47(1)(e)(iv)	3, 4, 5, 6	2
New site of manufacture for cannabis-based ingredient and new/revised manufacturing process for cannabis-based ingredient	47(1)(e)(iv)	2, 3, 4, 5, 6	3
Documentation			
1 Revised GMP certification with new manufacturing site name or letter notifying of name change.			
1 GMP certification for the new cannabis-based ingredient manufacturing site.			
2 Certificates of analysis for three representative batches of cannabis-based ingredient manufactured at the new site and/or using the new/revised process. Batches should be at least pilot scale manufactured using full production scale equipment.			
3 Amended manufacturing description (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for manufacturing description requirements).			
4 If applicable: Revised specifications/test methods for cannabis-based ingredient (refer to 2.1.4).			

5	Relevant stability data must be generated for three batches produced at the new site. The stability protocol and three months' stability data should be submitted with application. Additional stability data covering the entire shelf-life does not necessarily need to be supplied prior to the verification of the change. However, if the data are not supplied, the applicant must provide written assurance that stability data will be generated. The Medicinal Cannabis Agency must also be notified immediately if there are any significant problems identified or if the data indicate that the stability of product from the new process is different from that made at the original site, to the extent that the shelf life of the medicine would be affected.

2.1.4 Cannabis-based ingredient specifications and testing site and methods

Cannabis-based ingredient specifications and testing site/method	Regulation	Documentation required	Change category
Change in ownership or site name of testing site for cannabis-based ingredient	47(1)(e)(vi)	1	1
New cannabis-based ingredient testing site	47(1)(e)(vi)	2, 3 (if applicable), 4 (for non-pharmacopeial test methods)	2 or 3 (3 if test method validation required)
Revised cannabis-based ingredient specifications/test methods	47(1)(e)(iv)	3, 4 (for non-pharmacopeial test methods)	2 or 3 (3 if test method validation required)

Documentation	
1	Revised GMP certification with new testing site name or letter notifying of name change.
2	GMP certification of the new cannabis-based ingredient testing site.
3	Revised cannabis-based ingredient specifications (For tightening/loosening of specifications, stability history may be required to demonstrate that the product will remain within specification to end of shelf-life. The specifications the manufacturer applies must still meet the Quality Standard. The tests that apply to a cannabis-based ingredient can be found in Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand).
4	Test method validation data (test methods must have been validated in accordance with ICH guideline Q2(R1) Validation of Analytical Procedures: Text and Methodology).

2.1.5 Cannabis-based ingredient packing site

Cannabis-based ingredient packing site	Regulation	Documentation required	Change category
Change in ownership or site name of packing site for cannabis-based ingredient	47(1)(e)(vi)	1	1
New packing site for cannabis-based ingredient	47(1)(e)(vi)	2	1

Documentation	
1	Revised GMP certification with new packing site name or letter notifying of name change.
2	GMP certification of the new cannabis-based ingredient packing site.

2.1.6 Cannabis-based ingredient container closure system

Cannabis-based ingredient container closure system	Regulation	Documentation required	Change category
New container or closure and/or new pack size and/or new packaging material	47(1)(e)(v)	1, 2, 3 (unless otherwise justified)	2
Documentation			
1 Revised container closure specifications.			
2 Amended container closure system description (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for container closure system requirements).			
3 Stability data (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for stability requirements).			

2.1.7 Cannabis-based ingredient shelf life and storage conditions

Cannabis-based ingredient shelf life and storage conditions	Regulation	Documentation required	Change category
Decrease in storage temperature except for freezing (not due to out of specification and/or trend), with no change in shelf life and no other changes	47(1)(e)(viii)	1	1
Revised shelf life and/or storage conditions	47(1)(e)(viii)	1	2
Documentation			
1 Stability data supporting the revised shelf life and/or storage conditions (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for stability requirements).			

2.2 Proposed medicinal cannabis product changes

2.2.1 Trade name

Medicinal cannabis product trade name	Regulation	Documentation required	Change category
New product name to replace existing name	47(1)(e)(i)	1, 2	1
Documentation			
1 Proposed new trade name (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for trade name requirements).			
2 Revised labelling artwork (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for labelling requirements).			

2.2.2 Labelling

Medicinal cannabis product labelling	Regulation	Documentation required	Change category
Design or re-design of a New Zealand compliant label	47(1)(e)(ii)	1	1
Documentation			

1	Revised labelling artwork (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for labelling requirements).

2.2.3 Formulation

Medicinal cannabis product formulation	Regulation	Documentation required	Change category
Minor change in the formulation that does not affect stability	47(1)(e)(iii)	1, 2, 4, 5, 6, 7	2
Major change in the excipient and stability study included	47(1)(e)(iii)	1, 2, 3, 4, 5, 6, 7, 8, 9, 10	3

Documentation	
1	Revised formulation table.
2	Certificates of analysis obtained from a representative sample of three batches of the product (where the batches were at least 10% of the size of a full production scale batch).
3	Stability data (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for stability requirements).
4	If applicable: Revised labelling (refer to 2.2.2).
5	If applicable: Amended batch manufacturing description (must not be a significant manufacturing change refer to 2.2.4).
6	If applicable: Revised specifications/test methods for the cannabis-based ingredient (refer to 2.1.4).
7	If applicable: Revised specifications/test methods for the medicinal cannabis product (refer to 2.2.5).
8	If applicable: New or revised specifications for excipient(s) (refer to 2.2.5).
9	If applicable: Revised shelf life/storage conditions (refer to2.2.8).
10	For tablets and capsules: Comparative dissolution data for the proposed new and currently approved dosage product, using a discriminatory test, must be supplied for tablets and capsules. The data need to establish that there are no significant differences between the new and original formulations.

Note: A change in the cannabis-based ingredient or strength of an active ingredient requires a NMCP application not a CMCP application.

2.2.4 Manufacturing site and process

Medicinal cannabis product manufacturing site/process	Regulation	Documentation required	Change category
Change in ownership or site name of manufacturing site for medicinal cannabis product	47(1)(e)(vi)	1, 3	1
Change in commercial batch size (more than 10-fold the size of the original batches submitted for verification)	47	4 (if previous submitted batch sizes are no longer representative), 5	1
New site of manufacture for medicinal cannabis product	47(1)(e)(vi)	2, 3, 4, 7, 8	2
New/revised manufacturing process for medicinal cannabis product	47(1)(e)(iv)	4, 5, 6, 7, 8	2

New site of manufacture for medicinal cannabis product and new/revised manufacturing process for medicinal cannabis product	47(1)(e)(iv)	2, 3, 4, 5, 6, 7, 8	3
Documentation			
1	Revised GMP certification with new manufacturing site name or letter notifying of name change.		
2	GMP certification of the new medicinal cannabis product manufacturing site.		
3	If applicable: Revised labelling (refer to 2.2.2).		
4	Certificates of analysis for three representative batches of medicinal cannabis product manufactured at the new site or/and using the new process. Batches should be at least pilot scale manufactured using full production scale equipment.		
5	Amended manufacturing description (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for manufacturing description requirements).		
6	If applicable: Revised specifications for medicinal cannabis product (refer to 2.2.5).		
7	If applicable: Revised labelling (refer to 2.2.2).		
8	Relevant stability data must be generated for three batches produced at the new site. The stability protocol and three months' stability data should be submitted with application. Additional stability data covering the entire shelf-life does not necessarily need to be supplied prior to the verification of the change. However, if the data are not supplied, the company must provide written assurance that stability data will be generated. The Medicinal Cannabis Agency must also be notified immediately if there are any significant problems identified or if the data indicate that the stability of product from the new process is different from that made at the original process to the extent that the shelf life of the medicine would be affected.		
9	For tablets and capsules: Comparative dissolution data for representative batches of the dosage product using a discriminatory test, must be supplied for tablets and capsules. The data need to establish that there are no significant differences between the product manufactured using the new and original manufacturing processes/site.		

2.2.5 Specifications and testing site and method

Medicinal cannabis product specifications and testing site/method	Regulation	Documentation required	Change category
Change in ownership or site name of testing site for medicinal cannabis product	47(1)(e)(vi)	1	1
New medicinal cannabis product testing site	47(1)(e)(vi)	2, 3 (if applicable), 4 (for non-pharmacopeial test methods)	2 or 3 (3 if test method validation required)
Revised medicinal cannabis product specifications/test methods	47(1)(e)(iv)	3, 4 (for non-pharmacopeial test methods)	2 or 3 (3 if test method validation required)
Documentation			
1	Revised GMP certification with new testing site name or letter notifying of name change.		
2	GMP certification of the new medicinal cannabis product testing site.		
3	Revised medicinal cannabis product specifications (the specifications the manufacturer applies must still meet the Quality Standard. The tests that apply to a medicinal cannabis product can be found in Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand).		
4	Test method validation data. (test methods must have been validated in accordance with ICH guideline Q2(R1) Validation of Analytical Procedures: Text and Methodology).		

2.2.6 Packing site

Medicinal cannabis product packing site	Regulation	Documentation required	Change category
Change in ownership or site name of primary or secondary packing site for medicinal cannabis product	47(1)(e)(vi)	1	1
New primary packing site	47(1)(e)(vi)	2	1
New secondary packing site	47(1)(e)(vi)	2	1
Documentation			
1 Revised GMP certification with new packing site name or letter notifying of name change.			
2 GMP certification of the new medicinal cannabis product packing site.			

2.2.7 Container closure system

Medicinal cannabis product container closure system	Regulation	Documentation required	Change category
New container or closure and/or new pack size and/or new packaging material and revised shelf life and/or storage conditions	47(1)(e)(v)	1, 2, 4, 3 (unless otherwise justified)	3
Documentation			
1 Revised container closure specifications.			
2 Amended container closure system description (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for container closure system requirements).			
3 Stability data (is required if the packaging may be expected to be less protective than the currently approved packaging or a justification to show that the protection remains the same or is better).			
4 If applicable: Revised labelling.			

2.2.8 Shelf life and storage conditions

Medicinal cannabis product shelf life and storage conditions	Regulation	Documentation required	Change category
Decrease in storage temperature (not due to out of specification and/or trend) except for freezing, with no change in shelf life and no other changes.	47(1)(e)(vii)	1, 2	1
Revised shelf life and/or storage conditions	47(1)(e)(viii)	1, 2 (if applicable)	2
Documentation			
1 Stability data supporting the revised shelf life and/or storage conditions (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for stability requirements).			
2 Revised labelling artwork (refer to Part 3 of the Guidance on the Regulation of Medicinal Cannabis in New Zealand for labelling requirements).			

Section 3: How to submit a changed medicinal cannabis product application

3.1 Responsibilities of the licence holder

The Medicinal Cannabis Licence holder, Medicines Act 1981 licence holder or the owner of the verified product is legally responsible for all aspects of the medicinal cannabis product or cannabis-based ingredient in New Zealand, including any regulatory action relating to it. The licence holder/owner is responsible for ensuring the accuracy of any information submitted to the Agency in support of any CMCP. The applicant for a CMCP must be the applicant for the original NMCP. The product requiring a change needs to be listed on an appropriate licence under the Medicine Acts 1981 before verification of the change.

It is the responsibility of the licence holder to fully understand and, if necessary, get appropriate advice (legal or otherwise) on their obligations, including under the Medicines Act 1981, the Misuse of Drugs Act 1975 and the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and associated regulations, before submitting an application for a CMCP and throughout the period they hold a licence.

3.2 Submitting an application

When submitting an application for a CMCP, you must include:

- a completed CMCP application form
- a signed declaration form
- additional data supporting the change to the medicinal cannabis product or cannabis-based ingredient.

The CMCP application form is designed for you to complete electronically, following the guidance in this section. You must complete all fields of the form. For additional resources to help you compile an application, see section 1.3.

You must complete one copy of the application form for each unique product or ingredient.

A unique product is identified by its:

- trade name
- dose form
- active ingredient(s)
- strength.

For each product that has a different trade name, dose form, active ingredient(s) or strength, you will need to complete a separate form and application. Different sizes of the same product (eg, 10 ml and 20 ml) are considered to be one product, so you can include them in one application for

product assessment as long as the stability data supports the proposed shelf life and storage conditions for each product size.

When submitting several applications for similar products (eg, a product of varying strengths) you should state in the application, for every additional version, that the product is based on the named parent product.

> **Note**: If any change to a medicinal cannabis product or cannabis-based ingredient results in a new active ingredient, new strength, new dose form or new route of administration an NMCP application (not a CMCP application) is required. The changed product or ingredient should not be supplied until the new product or ingredient has been added to an appropriate licence.

3.3 Product details

Enter the verified product details (trade name, active ingredients and strength, and dosage form and verified route of administration) as stated on your Medicinal Cannabis Licence, Medicines Act licence or verification letter.

3.4 Licence holder and contact person details

A contact person may be a licence holder, or be acting on behalf of a Medicinal Cannabis Licence holder or a Medicines Act 1981 licence holder, or the owner of the product, to submit a CMCP application to the Agency.

3.4.1 New Zealand licence holder

You must submit all requested details of either the licence holder (the entity responsible for the product on the New Zealand market) including the type of licence held and the licence number, or the owner of the verified product. The licence holder/owner is considered to be the applicant for the CMCP application.

3.4.2 Contact person

The contact person is the person to whom the Agency will communicate on all matters (including the fee invoice) regarding a CMCP application. The contact person is the individual responsible for submitting the application and for responding to all correspondence. A contact person may be a licence holder, a director/partner, an authorised person or a responsible person, for the licensed activity. You should provide details of the contact person who is responsible for submitting the application and for responding to all correspondence. If applicable, include any letters of authorisation for a proposed contact person nominated to act on behalf of the licence holder, including details of the relationship between the contact person and the applicant.

3.5 Summary of proposed changes

Describe what proposed changes are to be made and the reasons for the proposed changes.

Summarise the current product details and the proposed product details for the proposed changes.

List the details of any overseas approvals, declined approvals or submissions for approval (if any) for each medicinal cannabis product included in your application. Include the country name and regulatory agency, along with the date of approval, declined approval or submission. Separate multiple entries by commas. If no approvals, declined approvals or submissions for approval exist for your product, enter 'Not applicable'.

> **Note**: If any overseas jurisdiction has approved your changed product, that does not mean it meets the Quality Standard in New Zealand. You are required to provide these details for information purposes only. The Agency will independently assess the changed product against the New Zealand Quality Standard.

3.6 Proposed changes

Check all proposed changes to a cannabis-based ingredient or medicinal cannabis product are specifically identified and applied for. The change must be supported by evidence to satisfy the Agency that the change to the medicinal cannabis product or cannabis-based ingredient being supplied to the market still meets the New Zealand medicinal cannabis quality standard.

Refer to section 2 for the documents to be provided with each change.

> **Note**: When the Agency assesses a change to a product or ingredient, only those changes specifically identified and applied for in the application form are covered. Changes included in any accompanying documentation but not specifically identified in the change application form and consequently not assessed as changes, are not included in any verification that the product or ingredient meets the quality standards for the changes in the product or ingredient.