**Application Form**

|  |  |
| --- | --- |
| medicinal cannabisApplication for an assessment of a Changed Medicinal Cannabis ProductMisuse of Drugs (Medicinal Cannabis) Regulations 2019 | CP |

|  |
| --- |
| **Office use only** |
| Contact person name: |  |
| Licence holder: |  |
| Date application received: |  |
| Assigned to: |  |

INFORMATION FOR APPLICANTS

Use this application form to apply for an assessment of a Changed Medicinal Cannabis Product (CMCP). Before completing this application form, read **Part 5**: **Guidance for a New Medicinal Cannabis Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*. This CMCP application form follows the structure of **Part 5**.

A contact person may be a licence holder, a director/partner, an authorised person, or a responsible person.

For the application to be considered, you must complete all the relevant sections of the application form and provide the necessary information.

While this form provides space for you to provide the required information, you will also need to present the supporting information as clearly marked separate attachments.

During its assessment of the application, the Medicinal Cannabis Agency (the Agency) may request further information from you.

When the Agency receives your application, it will invoice you a fee of $345 (including GST) for an initial check of the application. This fee is non-refundable.

If the application appears to be in order, the Agency will invoice you for the CMCP assessment fee.

The assessment of your CMCP will not start until you have paid the full assessment fee. The assessment fee is non-refundable.

|  |
| --- |
| **INSTRUCTIONS FOR COMPLETING THE APPLICATION** |
| * Additional documents required by Section 2 of **Part 5** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*, should be provided in clearly named attachments.
* Section 3 of **Part 5** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* and Section 3 of this form both outline the supporting information that you are required to submit with your application based on what type of changes you are applying for. Please attach all required documents and clearly name them in Section 3 of this form so that your application can proceed.
 |
| **APPLICATION FORM SUBMISSION** |
| * For electronic submission, scan the completed application form and supporting documents to the Medicinal Cannabis Agency (medicinalcannabis@health.govt.nz). You must ensure that the emailed form is legible and complete.
* If you are unable to scan and email the application form, you can post a copy to:

Medicinal Cannabis AgencyMinistry of HealthPO Box 5013Wellington 6140* Keep a copy of the completed application form for your records.
 |

# Application for assessment of a Changed Medicinal Cannabis Product

The sections of this form follow the structure and section names of **Part 5** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

## Section 3.3: Verified product details

|  |  |
| --- | --- |
| Trade name: |  |
|  |  |
| Active ingredients: |  |
|  |  |
| Strength of active ingredients: |  |
| THC: |  |
|  |  |
| THCA: |  |
|  |  |
| CBD: |  |
|  |  |
| CBDA: |  |
|  |  |
| Dosage form: |  |
|  |  |
| Verified route of administration: |  |
|  |  |

## Section 3.4: Licence holder and contact person details

The contact person is the person with whom the Agency will communicate on all matters (including the fee invoice) related to this application for an assessment of a Changed Medicinal Cannabis Product.

### S3.4.1 New Zealand licence holder

Tick the appropriate box below and complete the details underneath.

[ ]  This application is being made under a current Medicinal Cannabis Licence (with supply as a specified activity) or a licence issued under the Medicines Act 1981,[[1]](#footnote-1) as detailed below.

|  |  |
| --- | --- |
| Licence type: |  |
|  |  |
| Name of licence holder: |  |
|  |  |
| Current licence number: |  |

OR

[ ]  This application is being made by the applicant who submitted the original New Medicinal Cannabis Product for which this change has been requested. The applicant does not hold a Medicinal Cannabis Licence (with supply as a specified activity) but their verified product(s) is currently named on an appropriate licence under the Medicines Act 19811 for supply, as detailed below.

|  |  |
| --- | --- |
| Licence type: |  |
|  |  |
| Name of licence holder: |  |
|  |  |
| Name of applicant: |  |

### S3.4.2 Contact person

|  |  |
| --- | --- |
| Given name(s): |  |
|  |  |
| Surname: |  |
|  |  |
| Company name: |  |
|  |  |
| Job title / position held: |  |
|  |  |
| Relationship to licence holder: |  |
|  |  |
| Date of birth: |  |
|  |  |
| Physical address: |  |
| Street number and name: |  |
|  |  |
| Suburb: |  |
|  |  |
| Town/city: |  |
|  |  |
| Postcode: |  |
|  |  |
| Postal address: | ☐ Postal address same as physical address |
| PO Box: |  |
|  |  |
| Suburb: |  |
|  |  |
| Town/city: |  |
|  |  |
| Postcode: |  |
|  |  |
| Contact details: |  |
| Phone: |  |
|  |  |
| Email: |  |

## Section 3.5: Summary of proposed changes

**Description of change(s):**

**Summary of current and proposed details:**

| **Current product details** | **Proposed product details** |
| --- | --- |
| 1.
 |  |
| 1.
 |  |
| 1.
 |  |
|  |  |

**Acceptance overseas:**

## Section 3.6: Proposed changes

Check the box for the changes that apply to this application. See Section 2 in **Part 5** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* for a list of the documents you must submit for each type of application.

**Cannabis-based ingredient**

| **Cannabis-based ingredient trade name** | **Regulation** |  **Change category** | **Check box** |
| --- | --- | --- | --- |
| New product name to replace existing name | 47(1)(e)(i) | 1 |  |
| **Cannabis-based ingredient composition** | **Regulation** | **Change category** | **Check box** |
| Minor change in the composition of an active ingredient or ingredient that does not affect stability or safety | 47(1)(e)(iii) | 2 |  |
| **Cannabis-based ingredient manufacturing site/process** | **Regulation** | **Change category** | **Check box** |
| Change in ownership or name of manufacturing site for CBI | 47(1)(e)(vi) | 1 |  |
| Change in the commercial batch size (more than 10-fold the size of the original batches submitted for verification) | 47(1)(e)(iv) | 1 |  |
| New site of manufacture for CBI | 47(1)(e)(vi) | 2 |  |
| New/revised manufacturing process for CBI  | 47(1)(e)(iv) | 2 |  |
| New site of manufacture for CBI and new/revised manufacturing process for CBI  | 47(1)(e)(iv) | 3 |  |
| **Cannabis-based ingredient specifications and testing site/method** | **Regulation** | **Change category** | **Check box** |
| Change in ownership or name of testing site for CBI | 47(1)(e)(vi) | 1 |  |
| New CBI testing site | 47(1)(e)(vi) | 2 or 3 (if submission of test method validation required) |  |
| Revised CBI specifications/test methods  | 47(1)(e)(iv) | 2 or 3 (if submission of test method validation required) |  |
| **Cannabis-based ingredient packing site** | **Regulation** | **Change category** | **Check box** |
| Change in ownership or site name of packing site for CBI | 47(1)(e)(vi) | 1 |  |
| New packing site for CBI | 47(1)(e)(vi) | 1 |  |
| **Cannabis-based ingredient container closure system** | **Regulation** | **Application level** | **Check box** |
| New container or closure and/or new pack size and/or new packaging material | 47(1)(e)(v) | 2 |  |
| **Cannabis-based ingredient shelf life and storage conditions** | **Regulation** | **Change category** | **Check box** |
| 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)(viii) | 1 |  |
| Revised shelf life and/or storage conditions | 47(1)(e)(viii) | 2 |  |

**Medicinal Cannabis product**

| **Medicinal cannabis product trade name** | **Regulation** | **Change category** | **Check box** |
| --- | --- | --- | --- |
| New product name to replace existing name | 47(1)(e)(i) | 1 |  |
| **Medicinal cannabis product labelling** | **Regulation** | **Change category** | **Check box** |
| Design or re-design of a New Zealand compliant label | 47(1)(e)(ii) | 1 |  |
| **Medicinal cannabis product formulation** | **Regulation** | **Change category** | **Check box** |
| Minor change in the formulation or change in overage of an active ingredient or excipient that does not affect stability or safety | 47(1)(e)(iii) | 2 |  |
| Change in the excipient and stability study included | 47(1)(e)(iii) | 3 |  |
| **Medicinal cannabis product manufacturing site/process** | **Regulation** | **Change category** | **Check box** |
| Change in ownership or site name of manufacturing site for medicinal cannabis product | 47(1)(e)(vi) | 1 |  |
| Change in commercial batch size (more than 10-fold the size of the original batches submitted for verification) | 47 | 1 |  |
| New site of manufacture for medicinal cannabis product | 47(1)(e)(vi) | 2 |  |
| New/revised manufacturing process for medicinal cannabis product | 47(1)(e)(iv) | 2 |  |
| New site of manufacture for medicinal cannabis product and new/revised manufacturing process for medicinal cannabis product | 47(1)(e)(iv) | 3 |  |
| **Medicinal cannabis product specifications and testing site/method** | **Regulation** | **Change category** | **Check box** |
| Change in ownership or name of testing site for medicinal cannabis product | 47(1)(e)(vi) | 1 |  |
| New medicinal cannabis product testing site | 47(1)(e)(vi) | 2 or 3 (3 if submission of test method validation required) |  |
| Revised medicinal cannabis product specifications/test methods | 47(1)(e)(iv) | 2 or3 (3 if submission of test method validation required) |  |
| **Medicinal cannabis product packing site** | **Regulation** | **Change category** | **Check box** |
| Change in ownership or name of primary or secondary packing site for medicinal cannabis product | 47(1)(e)(vi) | 1 |  |
| New primary packing site | 47(1)(e)(vi) | 1 |  |
| New secondary packing site | 47(1)(e)(vi) | 1 |  |
| **Medicinal cannabis product container closure system** | **Regulation** | **Change category** | **Check box** |
| 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) | 3 |  |
| **Medicinal cannabis product shelf life and storage conditions** | **Regulation** | **Change category** | **Check box** |
| 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 |  |
| Revised shelf life and/or storage conditions | 47(1)(e)(viii) | 2 |  |

# Statutory declaration

A CMCP application for assessment may be submitted to the Agency by a person acting on behalf of a Medicinal Cannabis Licence holder or applicant or on behalf of a Medicines Act 1981 licence holder or applicant. Include any letters of authorisation for all proposed contact persons nominated to act on behalf of the licence holder or applicant.

|  |  |
| --- | --- |
| I, *[full name]* |  |
| of *[place]* |  | *[occupation]* |  |
| solemnly and sincerely declare that I am authorised to complete this application on behalf of |
|  |
| *[name of applicant or entity]* |

**and I confirm that the ingredient, or product and all ingredients of the product:**

1. have not been adulterated as defined in Regulation 14(2) of the Misuse of Drugs (Medicinal Cannabis) Regulations 20192, and contains no prescription medicines or controlled drugs other than cannabis or cannabis-based ingredients

3. have been tested using methods that have been validated according to [ICH guideline Q2 (R1) Validation of analytical procedure: text and methodology](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-2-r1-validation-analytical-procedures-text-methodology-step-5_en.pdf), where test method validation is required

4. have not been subject to any decontamination treatment that adversely affects the quality, including the use of ethylene oxide

5. the test results provided herein were obtained from a representative sample of three batches of the ingredient or product (where the batches were at least 10% of the size of a full production scale batch)

**and I confirm that** all active ingredients and cannabinoids present in the product are derived from *Cannabis sativa* only

**and I:**

6. agree that the information provided in this application may be shared with other agencies, including the New Zealand Police and the Ministry for Primary Industries

7 permit the publication, if verified against the minimum quality standard, any change to the trade name of the product, the active ingredients, strength of active ingredient, pack size(s), recommended method of administration and name of licence holder.

8. declare that the information I have supplied in this application is, to the best of my knowledge and belief, true and correct in every particular, and I make this declaration in the knowledge that a person making a false declaration is liable to prosecution under section 15 of the Misuse of Drugs Act 1975 (False statements) and regulation 78 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature |  | Date |

|  |  |
| --- | --- |
| Declared at*(place – for example, name of town or city):* |  |

|  |  |
| --- | --- |
| Before me*(name of official witness):*[[2]](#footnote-2) |  |

|  |  |
| --- | --- |
| Signature of official witness: |  |

1. Appropriate licences are a Licence to Manufacture Medicines, a Licence to Pack Medicines, a Licence to Sell Medicines by Wholesale and a Licence to Operate Pharmacy. You must make a separate application to amend an existing Medicines Act 1981 licence. [↑](#footnote-ref-1)
2. Authorised witnesses include (see [section 9 of the Oaths and Declarations Act 1957](http://www.legislation.govt.nz/act/public/1957/0088/latest/DLM314584.html) for complete list):

	* a justice of the peace (JP)
	* a solicitor or notary public – you may have to pay for their services
	* a Registrar or Deputy Registrar of the District Court or the High Court
	* authorised staff in some government agencies. [↑](#footnote-ref-2)