**Application Form**

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| medicinal cannabisApplication to Amend a Medicinal Cannabis LicenceRegulation 47, Misuse of Drugs (Medicinal Cannabis) Regulations 2019 | LA |

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| **INFORMATION FOR APPLICANTS** |
| * Use this application form to make an application to amend a current medicinal cannabis licence. Please refer to the ***Guidance for Applicants for a Medicinal Cannabis Licence*** document prior to completing this application.
* Regulation 47 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 specifies the changes to a licence that require prior approval and therefore an application to amend the licence must be made.
* You must submit the application to the Medicinal Cannabis Agency (the Agency) at least 60 days before the proposed changes are intended to take effect.
* The proposed changes **must not** be implemented until approval is granted.
* If you are applying for a change that affects the location’s security arrangements, an inspection of the location may be required prior to approval of the amendment.
* If you are applying for a new or additional location for any activity, an inspection of the location will be required prior to approval of the amendment.
* If you are applying for a new activity at an existing location, an inspection of the location may be required prior to approval of the amendment.
* If you wish to make any additional changes after the application to amend your licence has been accepted for assessment, but before approval is granted, you should withdraw your initial application and submit a new amendment application with all the requested changes.
* Only one application to amend the licence can be processed at a time.
* During the assessment of the amendment application, the Agency may request further information from you.
* Information you provide in the amendment application may be shared with other agencies, including the New Zealand Police and the Ministry for Primary Industries.
* All amendment applications occur an initial check fee, however, an activity fee only applies where your amendment application relates to:
	+ the addition of one or more new types of licensed activity to the licence, or a new or additional location
	+ any change relating to a location used for a type of licenced activity if the change affects the location’s security arrangements.
* Changes to the responsible persons must not be made without prior approval from the Director-General of Health.
* If you are intending to make additions to the responsible person(s), they will be required to undergo Ministry of Justice checks.
* You must provide identification documents for each of these persons.
* Applying to add export-only cannabis-based ingredients or medicinal cannabis products to your supply activity requires an amendment application. You need to supply evidence that the products are manufactured in compliance with Good Manufacturing Practice (GMP).
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| **INSTRUCTIONS FOR COMPLETING THE APPLICATION** |
| * Complete all sections of this document.
* Depending on the change(s) you wish to make, you may also be required to complete the relevant activity sections of *Form A: Application for a Medicinal Cannabis Licence* and submit them with this application.
* While this form has space for you to provide the required information, you can also present the information as clearly marked separate attachments.
* Some changes may require you to resubmit material you have previously provided to the Agency to support the submitted application (eg, floor plans of the facility).
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# Section LA1: Application contact person

The application contact person will be the person who the Agency will communicate with on all matters to do with this application to amend a medicinal cannabis licence.

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| Given name(s): |  |

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| Surname: |  |

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| Position title: |  |

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| --- | --- |
| Phone: |  |

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| Email: |  |

# Section LA2: Current licence

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| Name of licence holder: |  |

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| Current licence number: |  |
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# Section LA3: Change(s) requested

**LA3.1** Indicate what change(s) you are requesting to be made to the licence.

[ ]  Changes to a responsible person.

[ ]  Adding cannabis-based ingredients or medicinal cannabis products for supply by export only.

[ ]  Adding samples of starting material, cannabis-based ingredients, or medicinal cannabis products for supply by export for testing, analysis and non-therapeutic research in quantities exceeding the amounts currently specified on the licence.

(Note: there are activity fees associated with the following amendments)

[ ]  Amend the purpose of an authorised activity specified on the licence.

[ ]  Add a specified activity to the licence.

[ ]  Changes that may affect the security arrangements at a location specified on the licence.

[ ]  Add an activity at an additional location.

**LA3.2** Provide a brief description of the requested change(s):

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[Continue on additional sheets if necessary.]

**LA3.3** Attach any additional documents required for the requested change(s).

* To amend the purpose of an activity specified on the licence, complete and submit:

[ ]  the appropriate activity section of *Form A* (ie, Sections B to F)

[ ]  supporting documents to complete the section (eg, security plan).

* To amend the supply activity to specify ingredients or medicinal cannabis products for export only, complete and submit:

[ ]  the appropriate activity section of *Form A* (ie, Section F)

[ ]  supporting documents to complete the section (eg, recall plan)

* To amend the supply activity to export samples for analytical, testing or research purposes, exceeding the amounts currently specified on the licence, complete and submit:

[ ]  the appropriate activity section of *Form A* (ie, Sections B or F as appropriate)

[ ]  justification for the amount proposed to be exported

[ ]  the name and address of the research organisation, analytical or testing laboratory.

* For changes to a responsible person, complete and submit:

[ ]  section A3 of *Form A* for every new responsible person

[ ]  identification documents for each new responsible person (see section A6).

* To add a specified activity to the licence, complete and submit:

[ ]  the appropriate activity section of *Form A* (ie, Sections B to F)

[ ]  supporting documents to complete the section (eg, security plan).

* To change anything at a location specified on the licence that may affect the security arrangements, complete and submit:

[ ]  the appropriate activity section of *Form A* (ie, Sections B to F)

[ ]  supporting documents to complete the section (eg, security plan, standard operating procedures).

* To add a location to the licence, complete and submit:

[ ]  the appropriate activity section of *Form A* (ie, Sections B to F)

[ ]  supporting documents to complete the section (eg, geographical plan, security plan, standard operating procedures, identification documents for additional responsible persons).

# Section LA4: Statutory Declaration

I, *[full name*]

of *[place] [occupation]*

solemnly and sincerely declare that I am authorised to complete this application to amend the current medicinal cannabis licence on behalf of the licence holder, and I:

1. agree to provide any further information as required by the Licensing Authority
2. agree for the information provided in this application to be shared with other agencies including the New Zealand Police and the Ministry for Primary Industries
3. declare 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).

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

Signature Date

(An electronic signature is acceptable)

Declared at (place – for example, name of town or city): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Before me (name of official witness)[[1]](#footnote-2), [[2]](#footnote-3): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of official witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (An electronic signature is acceptable)

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| CHECKLIST |
| Before submitting the application, check that the following sections are completed and that you have attached the documents listed.☐ Sections LA1 to LA4.☐ The appropriate section(s) of Form A; Sections B to F.☐ Security plans and operational procedures for all activities and locations for which you have applied.For changes to responsible persons.☐ Form A Section A3 for each new responsible person.☐ Identification documents for responsible persons affected by the change.For addition of export-only cannabis-based ingredients and medicinal cannabis products to the supply activity.☐ Form A section F3.☐ Evidence that the cannabis-based ingredient or medicinal cannabis product in manufactured to GMP and is acceptable to the importing country.☐ Recall plan for the ingredients and medicines to be exported.For export of samples for research, analytical or testing purposes, exceeding the amounts currently specified on the licence.☐ Form A section F3.☐ Justification for the amount proposed to be exported.☐ The name and address of the research organisation, analytical or testing laboratory. |

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| **HOW TO SUBMIT APPLICATION FORM** |
| * Save the completed application form as a Word or copy-enabled PDF document.
* Do not submit photos of the application form.
* Attach supporting documents as separate, appropriately referenced documents. Do not submit supporting documents altogether as a single document. This delays the assessment.
* Email the completed application form and supporting documents to the Medicinal Cannabis Agency (medicinalcannabis@health.govt.nz).
* If you are unable to email the application form and supporting documents, you can post a copy to:

Medicinal Cannabis AgencyMinistry of HealthPO Box 5013Wellington 6145* Keep a copy of the completed application form and supporting documents for your records.
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1. 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)
2. The application may be returned if the declaration has not been witnessed by an official witness. [↑](#footnote-ref-3)