**Application Form**

|  |  |
| --- | --- |
| medicinal cannabisApplication for the assessment of a New Medicinal Cannabis Product: Type 3 Starting Material for ExportMisuse of Drugs (Medicinal Cannabis) Regulations 2019 | SM |

|  |
| --- |
| **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 Starting Material for Export (SME). Before completing this application form, read **Part 3**: **Guidance for a New Medicinal Cannabis Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*. This SME application form follows the structure of **Part 3**.

A contact person may be a licence holder, a director/partner or a responsible person for the licensed activity.

For the application to be considered, you must complete all of 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 assessment of your application, the Medicinal Cannabis Agency (the Agency) may request further information from you.

Once the Agency receives your application, you will be invoiced $345 (including GST) for the initial check of your application. This fee is non-refundable.

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

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

|  |
| --- |
| **INSTRUCTIONS FOR COMPLETING THE APPLICATION** |
| * While this form includes space for you to provide the information required by Section 2 of **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*, you may provide any additional information in clearly named attachments.
* Section 3 of **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* and Section 3 of this form both outline the supporting information you are required to submit with your application 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 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 6145* Keep a copy of the completed application form for your records.
 |

# Application for assessment of Starting Material for Export

The sections of this form follow the structure and section names of **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

## Section 2.3: Proposed product details

*At a minimum, identifying information should include a unique identifier (maximum of 12 characters), material description, weight, package size, country of origin, destination, and date export will be completed.*

|  |  |  |
| --- | --- | --- |
| S2.3.1 | Type of application: | Type 3: starting material for export |
|  |  |  |
| S2.3.2 | Consignment name/Unique identifier: |  |
|  |  |  |
| S2.3.2 | Material description |  |
|  |  |  |
| S2.3.2 | Total weight |  |
|  |  |  |
| S2.3.2 | Package size(s) |  |
|  |  |  |
| S2.3.2 | Country of Origin | New Zealand |
|  |  |  |
| S2.3.2 | Destination country/ies |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| S2.3.2 | Date export will be completed |  |

## Section 2.5: Licence holder and contact person details

The contact person is the person with whom the Agency will communicate on all matters relating to this application, including invoicing.

### S2.2.1 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) as detailed below.

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

OR

☐ This application is being made at the same time as an application for a Medicinal Cannabis Licence (with supply as a specified activity) as detailed below.

|  |  |
| --- | --- |
| Licence name: |  |
|  |  |
| Name of applicant: |  |

### S2.5.2 Applicant details

|  |  |
| --- | --- |
|  |  |
| Company name: |  |
|  |  |
| Company registration number: |  |
|  |  |
| Physical address: |  |
| Street number and name: |  |
|  |  |
| Suburb: |  |
|  |  |
| Town/city: |  |
|  |  |
| Postcode: |  |
|  |  |
| Business location address: | ☐ Same as physical address |
| Street number and name: |  |
|  |  |
| Suburb: |  |
|  |  |
| Town/city: |  |
|  |  |
| Postcode: |  |
|  |  |
| Contact person for this application: |
| Name: |  |
|  |  |
| Phone: |  |
|  |  |
| Email: |  |
|  |  |
| Title/position: |  |
|  |  |
| Relationship to licence holder: |  |

## Section 2.8: Product packaging and storage conditions

*There are no specific requirements for packaging a starting material for export. Include a description of the packaging. The packaging should be identifiable (see Section 2.3.2) and should protect the material during transport.*

### Primary packaging

|  |  |
| --- | --- |
| Materials and description: |  |

### Secondary packaging*(if applicable)*

|  |  |
| --- | --- |
| Materials and description: |  |

## Section 2.9: Good Manufacturing Practice certification/ISO accreditation

### S2.9.2 Testing of the starting material

|  |  |
| --- | --- |
| Name of testing site: |  |
|  |  |
| Testing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence:/ ISO/IEC 17025 accreditation |  |
|  |  |
| GMP certification/ISO accreditation date of expiry: |  |
|  |  |
| Testing steps carried out at this site: |  |

|  |  |
| --- | --- |
| Name of testing site: |  |
|  |  |
| Testing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence: ISO/IEC 17025 accreditation |  |
|  |  |
| GMP certification/ISO accreditation date of expiry: |  |
|  |  |
| Testing steps carried out at this site: |  |

|  |  |
| --- | --- |
| Name of testing site: |  |
|  |  |
| Testing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence: ISO/IEC 17025 accreditation |  |
|  |  |
| GMP certification/ISO accreditation date of expiry: |  |
|  |  |
| Testing steps carried out at this site: |  |

# Section 3: Additional data required in an application for starting material for export

See Appendix 1 in **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* for a list of the documents you must submit for this application.

|  |  |
| --- | --- |
|  | **Name of attached document(s)** |
| GMP certification/ISO/IEC 17025 accreditation of starting material testing site (s) |  |
| Test results (Certificates of Analysis) Detailing:Microscopic and macroscopic identification of cannabisMicrobiological contamination Heavy metals Pesticides: * 0.020 ppm of Abamectin
* 0.020 ppm of Bifenazate
* 0.100 ppm of Bifenthrin
* 0.010 ppm of Chlormequat chloride
* 0.020 ppm of Daminozide
* 0.020 ppm of Etoxazole
* 0.020 ppm of Fenoxycarb
* 0.010 ppm of Imazalil
* 0.020 ppm of Imidacloprid
* 0.020 ppm of Myclobutanil
* 0.020 ppm of Paclobutrazol
* 0.050 ppm of Pyrethrins (I and II)
* 0.010 ppm of Spinosad (Spinosyn A and Spinosyn D)
* 3.000 ppm of Spiromesifen
* 0.020 ppm of Spirotetramat
* 0.020 ppm of Trifloxystrobin

Absence of aflatoxins Ochratoxin A Foreign matter Loss on drying Total ash  |  |
| Non-pharmacopoeial test method validation if applicable |  |
| Letter of authorisation for contact person from licence holder |  |

# Statutory declaration

A Starting Material for Export application for assessment may be submitted to the Agency by a person acting on behalf of a Medicinal Cannabis 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 starting material for export:**

1. has not been adulterated as defined in Regulation 14(2) of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

2. contains no prescription medicines or controlled drugs other than cannabis

3. has 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. has not been subject to any decontamination treatment that adversely affects the quality of the starting material, including the use of ethylene oxide

**and I:**

5. confirm that the test results provided herein were obtained from a representative sample of the lot of starting material for export and is representative of each consignment when exported

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. 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):*[[1]](#footnote-1) |  |
| Signature of official witness: |  |

 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.
1. [↑](#footnote-ref-1)