# Application - Medicinal Cannabis Permit - Cultivation and Production

This application form seeks authorisation from the Secretary of the Department of Health and Aged Care to undertake the cultivation and production of cannabis, for medicinal and scientific purposes in accordance with section 8P of the [*Narcotic Drugs Act 1967*](https://www.legislation.gov.au/Series/C1967A00053)(Cth).

Once completed, email this form along with all relevant supporting documentation to the Office of Drug Control at mcs.application@health.gov.au.

**Screening Questions** (*select yes/no*)

Is a licence currently held under the *Narcotic Drugs Act 1967* authorising the cultivation of cannabis plants and the production of cannabis or cannabis resin?
[ ]  **Yes**[ ]  **No**

***If this is the first permit for this activity under the licence or at this premises:***

Does the site/floor plan intended to be used for this activity match those on the licence?
[ ]  **Yes**[ ]  **No**

Have any imposed licence conditions that are required to be met prior to the submission of the first permit application for this activity, been met?
[ ]  **Yes**[ ]  **No**

When will the site be ready for a pre-commissioning inspection to be conducted? (please provide date)

***If you have previously held a permit for this activity at this premises:***

Is the site/ floor plan unchanged since you last applied for a permit e.g. no changes to fences, additional vaults or security changes?
[ ]  **Yes**[ ]  **No**

*(If site changes have already been approved by a licence variation, please provide further details under Part 3 of this application)*

If ‘Yes’ to all the above, proceed to Part 1. If ‘No’ to any of the above, contact the Office of Drug Control for next steps by email at mcs.application@health.gov.au.

## Part 1 - General details

| 1. Licence holder details
 |
| --- |
| **Licence holder name** |  |
| **Licence number** |  |
| **Person(s) authorised to discuss this application with the Office of Drug Control, if different to approved contacts** | Name |       | Phone |       | Email |       |
| Name |       | Phone |       | Email |       |

|  |
| --- |
| 1. **Licensed premises details for this permit**
 |
| **Address** | Street |       |
| Town/ Suburb |       | State |       | Postcode |       |

## Part 2 - Existing cannabis material held (*for existing permit holders only*)

| Existing permit number |       |
| --- | --- |
| Expiry date |       |

| Type of cannabis material | Estimated maximum quantity still in possession or control of the licence holder at the expiry date | Comments |
| --- | --- | --- |
| **Seeds** (units) | Low THC |  |  |
| High THC |  |  |
| **Cannabis plants (units)**(a plant unit is one that has formed roots) | Low THC |  |  |
| High THC |  |  |
| **Cannabis** (kg, expressed as dry weight at 10% moisture content) | Low THC |  |  |
| High THC |  |  |
| **Cannabis resin** (kg) | Low THC |  |  |
| High THC |  |  |
| **Other** (describe in comments) | Low THC |  |  |
| High THC |  |  |

## Part 3 - Overview of activities

| Select which activity(s) the licence holder intends to undertake under this permit |
| --- |
| [ ] Cultivation of cannabis[ ] Production of cannabis[ ] Production of cannabis resin[ ]  Tissue culture[ ]  Maintain genetic stock (cultivation only)[ ]  Scientific research – (provide details)[ ]  Other – (provide details)**Provide details of the activities intended to be undertaken under the cultivation and production permit. If a permit has been previously held for this activity, please provide details of any changes or updates.*****Note:*** *Include a justification of the quantities proposed in schedule 1 below. This should include method of production, storage, and details of how the end product will be used (i.e. cannabis, cannabis resin or seed, and purpose of supply/ retention). Include the estimated number and period of crop cycles/ batches for intended cultivation and production over the twelve-month permit period.****Note****: Tissue culture related activities must not be precluded by the licence. If the licence currently includes an imposed condition precluding such activities, you must contact the Office of Drug Control for next steps as a licence variation will be required. If the licence holder intends to undertake activities relating to tissue culture (and is not precluded by the licence from doing so), please provide details such as growth mediums, storage methods and use of tissue culture*. |
|       |

## Part 4 - Propagation materials

| Tick and complete all that apply | Name and contact of the entity that propagation material intended to be obtained from | Type | Quantity of starting material to be obtained | Estimated losses (%) during the propagation phase |
| --- | --- | --- | --- | --- |
|[ ]  **Seeds** |  | **Low THC** |  |  |
|  |  |  | **High THC** |  |  |
|[ ]  **Cuttings** |  | **Low THC** |  |  |
|  |  |  | **High THC** |  |  |
|[ ]  **Other (e.g. tissue culture)** |  | **Low THC** |  |  |
|  |  |  | **High THC** |  |  |

Please attach a copy of any relevant contract/ invoice or proforma invoice from the entities that the licence holder intends to obtain the propagation materials

## Part 5 – Permit details

|  |  |  |
| --- | --- | --- |
| **Proposed permit start date** | Click here to enter a date. | **Permits will be granted for a standard 12 months from date of grant** |

|  |
| --- |
| **Schedules:** |
| ***Note****: Refer to the* ***guidance document*** *“Guidance: Applying for a medicinal cannabis permit for medicinal or scientific purposes – Cultivation and production activities” for assistance to complete the schedules below.* |

### Schedule 1: Cultivation and production activities

Types and quantities of medicinal cannabis proposed be obtained, cultivated, or produced under the relevant licence at this premises:

|  |  |
| --- | --- |
|  | **Quantity** |
| **Low THC ≤ 1%** | **High THC > 1%** |
| **Genetics** | Seeds | *Total* ***units*** *proposed to be* ***obtained*** *from other sources over the life of the permit* |       |       |
| *Total* ***units*** *proposed to be* ***harvested*** *over life of permit* |       |       |
| *Maximum* ***units*** *authorised to be on the premises at* ***any one time*** |       |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | **Quantity** |
|  |  | *\*For this purpose, a plant unit is one that has formed roots* | **Low THC ≤ 1%** | **High THC > 1%** |
| **Cultivation** | Plants | *Total* ***units*** *of plants\* proposed to be obtained from other sources over the life of the permit* |       |       |
| *Total* ***units*** *of plants\* proposed to be* ***cultivated*** *over the life of the permit (from seed, tissue culture or cuttings)* |       |       |
| *Maximum* ***units*** *of plants\* proposed to be on the premises at* ***any one time*** |       |       |
| **Production** | Cannabis | *Total quantity of cannabis proposed to be produced over the life of this permit* ***(kg)******dry weight at 10% moisture content*** |       |       |
| *Maximum quantity of cannabis proposed to be on the premises at* ***any one time (kg) dry weight at 10% moisture content*** |       |       |
| Cannabis resin | *Total quantity of cannabis resin proposed to be produced over the life of this permit* ***(kg)*** |       |       |
| *Maximum quantity of cannabis resin proposed to be on the premises at* ***any one time (kg)*** |       |       |
|  | Waste | *Total waste proposed* ***to be stored*** *on the premises before authorised disposal* ***(kg)******dry weight at 10% moisture content*** |       |       |

## Part 7 - Supply

List below the primary entities (as known at this time) that will receive cannabis, cannabis resin or cannabis plant material produced or generated under this permit. Please attach copies of any relevant contracts in accordance with section 9(c) of the *Narcotic Drugs Regulation 2016*, being ones I place between the applicant and a person who is authorised by a medicinal cannabis licence to do any of the follows: i) supply cannabis plants; ii) produce cannabis or cannabis resin; iii) manufacture a cannabis drug.

|  |
| --- |
| **Supply pathway - Cannabis or cannabis resin**  |
|  | **Supply pathway***Tick only the box(s) that the licence holder intends on supplying*  | **Provide a description of how the licence holder intends to supply under each supply pathway selected in the space provided below:**

|  |  |
| --- | --- |
| * **Supply to *Narcotic Drugs Act 1967* licenced manufacturer –** Name of licence holder
* **Supply to *Therapeutic Goods Act 1989* licenced manufacturer -**

Name of licence holder* **Testing or research –** Details of project
* **Supply to recipient under state and territory legislation –** Name of licence holder
* **Pharmacist in a public hospital –** name of recipient
 | * **Export –** Theoverseas importing country and *Customs Prohibited Export Regulations1956* Export licence number (if currently available)
* **Supply under the *Therapeutic Goods Act 1989* -** How will the licence holder ensure that supply is only to patients under the Special Access Scheme or an Authorised Prescriber?
* **Supply for extemporaneously-compounded medicinal cannabis products -** How will the licence holder ensure that supply is for the purposes of the recipient supplying an extemporaneously-compounded medicinal cannabis product in accordance with the *Therapeutic Goods Act 1989*
 |

 |
| 1 | [ ]  Transfer cannabis material to a different premises (at which the relevant licence authorises activities) |       |
| 2 | [ ]  Supply to the holder of a manufacture licence under the *Narcotic Drugs Act 1967* |       |
| 3 | [ ]  Supply to the holder of a licence under part 3-3 of the *Therapeutic Goods Act 1989* |       |
| 4 | [ ]  Supply to recipient under state and territory legislation  |       |
| 5 | [ ]  Supply for disposal or destruction |       |
| 6 | [ ]  Export |       |
| 7 | [ ]  Supply to a pharmacist in a public hospital  |       |
| 8 | [ ]  Supply for medical or scientific testing purposes |       |
| 9 | [ ]  Supply for the use in a clinical trial |       |
| 10 | [ ]  Supply forthe purposes of the recipient supplying extemporaneously-compounded medicinal cannabis products in accordance with the *Therapeutic Goods Act 1989* |       |

## Part 8- Attachments

To support your application, please provide the following documents:

|  |  |
| --- | --- |
| **Document:** | **Name of document**(and page number if applicable) |
| 1. Copies of all contracts that are in place between the applicant and another medicinal cannabis licence holder relevant to this application
 |       |
| 1. Details of how access will be provided to the premises for the purpose of inspecting such premises
 |       |
| 1. Evidence supporting the total area of the growing area to be used to cultivate the proposed plants
 |       |
| 1. Other relevant supporting documentation
 |       |

## Part 9- Additional requirements for an initial permit (only to be supplied if this is the first permit for this activity to be conducted at the licenced premises)

If this application is for the first permit for this activity relating to this location as authorised by the licence, the following documents must also be provided:

|  |  |
| --- | --- |
| **Document:** | **Name of document**(and page number if applicable) |
| 1. Risk management plan detailing management of risks associated with the activities authorised by the licence, including risks posed to the health and safety of people and risks posed to the environment
 |       |
| **Standard operating procedures and/or policies that deal with the following matters:** |  |
| 1. How persons entering the location will be controlled
 |       |
| 1. How unauthorised access at the location will be prevented, monitored, detected and recorded;
 |       |
| 1. The physical security being used to prevent, monitor and detect the loss of cannabis plants, cannabis drugs and starting materials relating to such drugs
 |       |
| 1. The loss and theft of cannabis plants, cannabis drugs and starting materials relating to such drugs
 |       |
| 1. The disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs
 |       |
| 1. The supply, delivery and transportation of cannabis plants, cannabis drugs and starting materials relating to such drugs
 |       |
| 1. The arrangements with emergency services (including a police service or relevant local government authority) to deal with loss, theft, spoilage, disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs
 |       |
| 1. The retention of records
 |       |
| 1. The engagement and retention of suitable staff
 |       |

## Part 10 - Privacy

The Office of Drug Control is part of the Australian Government Department of Health and Aged Care. The Office of Drug Control collects a variety of personal information in the course of performing its functions. Personal information is defined in the *Privacy Act 1988* (Cth) (Privacy Act). The applicant’s personal information is protected by law under the Privacy Act, which contains the Australian Privacy Principles. The Privacy Policy for this Department is available at [www.health.gov.au](http://www.health.gov.au).

## Part 11 - Declaration

|  |
| --- |
| Declaration  |
| * I am authorised by       to act on its behalf in providing the information contained in this form to the Secretary of the Department of Health and Aged Care;
* I declare that, to the best of my knowledge, this form is complete and all relevant information has been provided;
* I have read guidance document “*Guidance: Applying for a medicinal cannabis permit for medicinal or scientific purposes – Cultivation and production activities*” in addition to completing this application;
* I hold the appropriate authorisations in the licence to undertake activities in association with this permit, and the activities proposed in this application form are consistent with those proposed and accepted in the relevant licence application or variation;
* I acknowledge that providing incomplete or out of date information may result in delays for the processing of this permit application.

*Note: Providing false or misleading information may also constitute an offence (see Div 137 of the Criminal Code).* |

|  |  |
| --- | --- |
| Signature: | Name:            |
| **Date:**       |
| **Email:**       |

## Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

|  |  |  |  |
| --- | --- | --- | --- |
| **Date**  | **Version**  | **Amendments**  | **Approved by**  |
| December 2021  | 1.0  | Initial publication  | ODC  |
| July 2022 | 2.0 | Amendments to authorised supply pathways | ODC |