Australian Government
Department of Health and Aged Care
Office of Drug Control

# Application to vary a Medicinal Cannabis Permit – Cultivation and production for medicinal or scientific purposes

This application form seeks to vary a permit from the Secretary of the Department of Health and Aged Care relating to the cultivation and production of cannabis for medicinal and scientific purposes in accordance with the *Narcotic Drugs Act 1967*.

## Preliminary Questions

If **'Yes'** to all questions below, proceed to Section 1. If 'No' to any of the below, contact the Office of Drug Control (ODC) for next steps by email at: mcs.application@health.gov.au

1. Do you currently hold an active licence and permit under the *Narcotic Drugs Act 1967* authorising the cultivation and production of cannabis for medicinal or scientific purposes?

   ☐ Yes

   ☐ No

2. Does the permit that this application seeks to vary have a period greater than 3 months remaining until the expiry date?

   ☐ Yes

   ☐ No

3. Please confirm that there have been no changes which affect the licensed site (e.g. no changes to fences, additional vaults or security changes) or activity since you last applied for a permit, or a relevant licence variation has been approved by the ODC prior to submitting this permit application.

   ***Note:*** *If any variations have been approved or if you have confirmed a variation would not be required for any changes, please select 'yes' and provide further comments below.*

   ☐ Yes

   ☐ No

**Further comments (if required):**

4. Please confirm that there have been no changes to the Standard Operating Procedures (SOPs) and/or policies since you last applied for a permit (e.g. relating to disposal and destruction procedures, transport procedures, etc).

   ***Note**: If these updates have already been assessed during a licence variation or if you have confirmed a variation would not be required, please select 'yes' and provide further comments below.*

   ☐ Yes

   ☐ No

**Further comments (if required):**

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

## Important information

This is an application, to the Secretary of the Department of Health and Aged Care, made under section 10N of the *Narcotic Drugs Act 1967* (the Act) to vary a medicinal cannabis permit, granted under the Act, relating to a medicinal cannabis licence authorising cultivation and production for medicinal or scientific purposes.

Irrespective of the person(s) completing this permit variation application form, the licence holder is accountable for the accuracy of the information entered and submitted as part of the application, including any supporting documents.

The application may be withdrawn at any time before a decision has been made, but the application fee is not refundable. If you decide to withdraw your application, then an email to this effect should be sent to MCS.application@health.gov.au

## Implementation of variations

Variations sought through this permit application must not be implemented by the licence holder until a decision approving the application, when made by the delegate, is notified in writing by the ODC. It should be noted that the lodgment of an application to vary a permit does not constitute approval to commence or continue activities that would be unauthorised under an existing permit. Conducting authorised activities where facilities or security arrangements have not been approved may be a breach of the licence and unlawful.

## Privacy

The ODC collects a variety of personal information in the course of performing its functions. Personal information is defined in the *Privacy Act 1988* (Privacy Act). Your personal information is protected by law under the Privacy Act, which contains the Australian Privacy Principles. The ODC is part of the Australian Government Department of Health and Aged Care. The Privacy Policy for the Department is available at www.health.gov.au

## Providing Incorrect Information

Under Divisions 136 and 137 of the *Criminal Code Act 1995*, it is an offence to provide a false or misleading statement, information, or documents to the Commonwealth, including as part of an application for a permit.

## Section 1 - General applicant details

| Section 1.1 - Licence holder (applicant) details | |
|---|---|
| **Licence holder name** | |
| **Licence number** | |

| Section 1.2 - Application contacts | | | | I have been nominated as the application contact: *(select one option only)* | |
|---|---|---|---|---|---|
| **Application Contact #1** | | | | | |
| **First Name** | | **Surname** | | ☐ As I am an authorised person listed on the licence | ☐ As I have been declared as a nominated contact by the application signatory |
| **Phone Number** | | **Email Address** | | | |
| **Application Contact #2** | | | | | |
| **First Name** | | **Surname** | | ☐ As I am an authorised person listed on the licence | ☐ As I have been declared as a nominated contact by the application signatory |
| **Phone Number** | | **Email Address** | | | |

| Section 1.3 - Permit site details | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Provide details of the licensed premises at which authorised activities will be undertaken.** | | | | | | | |
| **Address Details** | **Street Number** | | **Street** | | | | |
| | **Suburb** | | | **State** | | **Postcode** | |

## Section 2 - Variation type

**The relevant variations requested in this permit variation application must be approved by the Delegate of the Secretary before commencing any proposed activities.**

Please select the applicable option/s below that correspond to the type of variation that is being applied for. Please note that each selected variation type will attract separate fees, see the ODC website at www.odc.gov.au for current fee information.

| **Section 2.1 - Details of the current cultivation and production permit** | |
|---|---|
| **Existing permit number** | |
| **Expiry date (DD/MM/YYYY)** | |

| **Section 2.2 - Variation type** *(select all that apply)* | | |
|---|---|---|
| **Type 1** | ☐ | **Change name of licence holder on the permit without changing the legal entity - *in conjunction with a licence variation application)***<br>*(Complete sections 3, 4, and 9 of this form)* |
| | ☐ | **Change to maximum quantities held at any one time - *without increasing total authorised quantities within the current permit period***<br>*(Complete sections 3, 6, 8 and 9 of this form)* |
| **Type 2** | ☐ | **Variation to authorised supply pathway categories - *add or remove supply pathway(s)***<br>*(Complete sections 3, 7, 8 and 9 of this form)* |
| **Type 3** | ☐ | **Change to total authorised quantities within the current permit period**<br>*(Complete sections 3, 6, 8 and 9 of this form)* |
| | ☐ | **Variation to authorised cultivation and production activities**<br>*(Complete sections 3, 5, 8 and 9 of this form)* |

## Section 3 - Overview of variation application

| Section 3.1 - Scope and purpose of variation |
|---|
| To ensure we have captured the full scope and purpose for your variation, please provide all relevant details of any changes required to be made. |
| **Overview of scope and purpose of variation:** |

## Section 4 – Variation to licence holder name on permit

| Section 4.1 - Variation to licence holder details on permit | |
|---|---|
| Please ensure you have also submitted a licence variation application to change the licence holder name. | |
| **Former licence holder name:** | **Updated licence holder name:** |
| | |

## Section 5 – Variation to authorised activities

| **Section 5.1 - Variation to authorised activities** | | |
|---|---|---|
| **Select which activities the licence holder intends to vary under this permit** | | |
| **Please select activities to be added or removed** *(if applicable):* | | **Cultivation / Production activities** |
| ☐ Add | ☐ Remove | Cultivation of cannabis plants |
| ☐ Add | ☐ Remove | Production of cannabis |
| ☐ Add | ☐ Remove | Production of cannabis resin |
| ☐ Add | ☐ Remove | Tissue culture activities **Note:** *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.* |
| ☐ Add | ☐ Remove | Maintain genetic stock (*cultivation only*) |
| ☐ Add | ☐ Remove | Scientific research - provide additional details |
| ☐ Add | ☐ Remove | Other - provide additional details below |

**Further details:**

## Section 6 – Variation to authorised quantities

### Section 6.1 – Change to permitted quantities

Please review the drop-down options below and:

- select the type of cannabis plant material/cannabis/cannabis resin that is being varied in this application
- ensure that the current permitted quantities are recorded below and provide the additional (or changed) amounts required
- any relevant supporting documentation is provided as an attachment

| Type of plant material | Quantity to be changed | Type | Current permitted quantities | Proposed quantities for the remainder of the permit period<br><br>**Note**: *if proposing lower quantities, use a negative (-) figure in this section.* |
|---|---|---|---|---|
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |

| Section 6.1 – Change to permitted quantities | | | | |
|---|---|---|---|---|
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |
| **Choose an item.** | **Choose an item.** | **Low THC** | | |
| | | **High THC** | | |

## Section 7 – Schedule 2 overview – Variation to supply pathways

**Section 7.1 - Proposed permit Supply pathways**

To vary the supply pathway categories on the permit, list 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 also provide copies of any relevant contracts/documents in accordance with section 9(c) of the *Narcotic Drugs Regulation 2016*, being ones in place between the applicant and a person who is authorised by a medicinal cannabis licence to do any of the following: i) supply cannabis plants; ii) produce cannabis or cannabis resin; iii) manufacture a cannabis drug.

**Supply Pathway items and requirements**

| **Item** | **Please select required response for each supply pathway** | **Supply pathway:**<br>*Please ensure any relevant options are selected* | **Licence holder requirements:**<br>*Please ensure any supporting documents are provided* | **Provide a brief description on any changes in the space provided below:**<br>*Please reference the name of any attachments provided as supporting documentation (for new proposed supply pathways).* |
|---|---|---|---|---|
| **Cannabis plants** | | | | |
| **1** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**)<br>The recipient holds a medicinal cannabis licence granted under the *Narcotic Drugs Act 1967* which authorises one or both of the following:<br>• cultivation of cannabis plants;<br>• production of cannabis or cannabis resin | If the licence holder intends on supplying cannabis plants to another entity licenced under *Narcotic Drugs Act 1967* for further cultivation, production or manufacture of cannabis.<br>- Provide name of licence holder<br>- The licence holder must make and keep a record of the name of the recipient<br>- Must ensure the recipients holds the appropriate licence/permit | |
| **2** | ☐ Proposed<br>☐ Remove | Transfer to different licensed premises authorised under the same licence ()<br>The relevant licence authorises, at the | If the licence holder is authorised for a different premises on the licence and intends to transfer cannabis plants between the sites for further | |

| Section 7.1 - Proposed permit Supply pathways | | | | |
|---|---|---|---|---|
| | | different premises, one or both of the following:<br>• cultivation of cannabis plants;<br>• production of cannabis or cannabis resin | cultivation/production and/or manufacture.<br>- Provide the relevant Site ID as authorised on the licence<br>- The licence holder must ensure that this would not result in inconsistency or breach of any licence conditions or permits relevant to the different premises | |
| **3** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**) for disposal or destruction<br>The recipient is authorised under Commonwealth, State or Territory legislation to undertake disposal or destruction activities | If the licence holder intends on supplying cannabis plants for the recipient for disposal or destruction of cannabis material.<br>- The licence holder must retain records of disposal<br>- Name of service provider<br>- Details of disposal procedures | |
| **4** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**) for testing<br>The recipient is authorised under Commonwealth, State or Territory legislation to undertake disposal or destruction activities | If the licence holder intends on supplying cannabis plants for the recipient to conduct testing or research on the supplied cannabis material.<br>- The licence holder must make and keep a record of the name of the recipient<br>- Provide supporting documentation if requested | |
| **Cannabis or cannabis resin** | | | | |
| **1** | ☐ Proposed<br>☐ Remove | Transfer to different premises authorised under the same licence<br>The relevant licence authorises, at the different premises, one or both of the | If the licence holder has multiple sites authorised on the licence and intends to transfer Cannabis or cannabis resin between the sites for further production | |

| Section 7.1 - Proposed permit Supply pathways | | | | |
|---|---|---|---|---|
| | | following:<br>• production of cannabis or cannabis resin<br>• manufacture of a cannabis drug | and/or manufacture.<br>- Provide Site ID as authorised on the licence<br>- The licence holder must ensure that this would not result in inconsistency or breach of any licence conditions or permits relevant to the different premises | |
| **2** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**)<br>The recipient holds a medicinal cannabis licence granted under the *Narcotic Drugs Act 1967* which authorises the following:<br>• manufacture of a cannabis drug | If the licence holder intends on supplying cannabis material to another entity licenced under *Narcotic Drugs Act 1967* for manufacture of cannabis.<br>- Provide name of licence holder<br>- The licence holder must make and keep a record of the name of the recipient.<br>- Must ensure the recipient holds the appropriate licence/permit.<br>- Please ensure that any supporting documents are provided. | |
| **3** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient)**<br>The recipient holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989*, and the cannabis or cannabis resin is supplied for use by that person in the manufacture of a medicine (within the meaning of that Act) | If the licence holder intends to supply cannabis material to a Good Manufacturing Practice (GMP) manufacturer licenced under the *Therapeutic Goods Act 1989*.<br>- The licence holder must make and keep a record of the name of the recipient.<br>- Please ensure that any supporting documents are provided (e.g. GMP licence/number). | |

| Section 7.1 - Proposed permit Supply pathways | | | | |
|---|---|---|---|---|
| **4** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**)<br>The recipient is authorised under State or Territory legislation to obtain, possess, and hold cannabis material for purposes including testing or research | If the licence holder intends on supplying cannabis material for the recipient to conduct testing or research on the supplied cannabis material.<br>- The licence holder must make and keep a record of the name of the recipient.<br>- Provide supporting documents if requested. | |
| **5** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**) for disposal or destruction<br>The recipient is authorised under Commonwealth, State or Territory legislation to undertake disposal or destruction activities | If the licence holder intends on supplying cannabis material for the recipient for disposal or destruction of cannabis material<br>- The licence holder must make and keep a record of the name of the recipient<br>- Provide supporting documents if requested | |
| **6** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**)<br>The licence holder has been issued a licence under the *Customs (Prohibited Exports) Regulations 1958* to export cannabis or cannabis resin | If the licence holder intends to export cannabis material to an overseas entity who is authorised to receive cannabis materials.<br>- The licence holder must make and keep a record of:<br>o the name of the importing country; and<br>o the export licence number<br>- Please ensure any supporting documents are provided. | |
| **7** | ☐ Proposed<br>☐ Remove | Supply to a pharmacist in a public hospital | If the licence holder intends on supplying cannabis material to a public hospital pharmacist who is authorised | |

| Section 7.1 - Proposed permit Supply pathways | | | | |
|---|---|---|---|---|
| | | | to dispense the drug in accordance with the *Therapeutic Goods Act 1989*.<br>- The licence holder must make and keep a record of the name of the hospital and the responsible pharmacist.<br>- The licence holder must ensure that supply is only to a pharmacist in a public hospital.<br>- Please ensure any supporting documents are provided. | |
| **8** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**)<br>The cannabis drug is supplied for use in a clinical trial that is, or is likely to be, approved (CTA) or notified (CTN) under the *Therapeutic Goods Act 1989* | If the licence holder intends on supplying cannabis materials for the use in a clinical trial under the *Therapeutic Goods Act 1989*.<br>- The licence holder must make and keep a record of the CTA or CTN number.<br>- Please ensure any supporting documents are provided. | |
| **9** | ☐ Proposed<br>☐ Remove | Supply to another person (**recipient**)<br>The recipient holds an approval under subsection 19(1) of the *Therapeutic Goods Act 1989* to supply cannabis or cannabis resin for use solely for experimental purposes in humans. | The recipient holds an approval under subsection 19(1) of the *Therapeutic Goods Act 1989* to supply cannabis or cannabis resin for use solely for experimental purposes in humans.<br>- The licence holder must obtain, and keep a record of, the details of the research and the manner in which the cannabis drug is to be used.<br>- Please ensure any supporting documents are provided. | |

| Section 7.1 - Proposed permit Supply pathways | | | | |
|---|---|---|---|---|
| **10** | ☐ Proposed<br>☐ Remove | Supply for the purposes of an extemporaneously-compounded medicinal cannabis product (**recipient**)<br>The cannabis drug is supplied to another person for the purposes of that person supplying an extemporaneously-compounded medicinal cannabis product (within the meaning of the Therapeutic Goods Regulations 1990) in accordance with the *Therapeutic Goods Act 1989.* | If the licence holder intends on supplying cannabis material for the purposes of the recipient to supply an extemporaneously-compounded medicinal cannabis product in accordance with the *Therapeutic Goods Act 1989.*<br>- The licence holder must make and keep a record of the name of the recipient.<br>- The licence holder must provide the relevant business address and at least one Healthcare Provider Identifier.<br>- The licence holder must ensure that supply is only to patients under the Special Access Scheme (SAS) or Authorised Prescriber (AP).<br>- Please ensure any supporting documents are provided. | |

## Section 8 – Attachments

To support your application, please provide relevant documents:

| **Document:** | **Name of document** (and page number if applicable) |
|---|---|
| Other relevant supporting documentation (add more rows as required) | |

## Section 9 – Declaration and consent

| **Declaration and Consent** | |
|---|---|
| a. I am authorised by the licence holder to act on its behalf in providing the information contained in this form to the Secretary of the Department of Health and Aged Care;<br>b. I declare that, to the best of my knowledge, this form is complete and all relevant information has been provided;<br>c. 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;<br>d. I hold the appropriate authorisations on the licence to undertake activities in association with this permit, and the activities proposed in this application form are consistent with those approved on the current medicinal cannabis licence;<br>e. I acknowledge that providing incomplete or out of date information may result in delays for the processing of this permit application.<br>*Note: Providing false or misleading information may also constitute an offence (see Div 137 of the Criminal Code).* | |
| **Signature:** or print out and sign: | **Name:** |
| | **Date:** |
| | **Email:** |
| | **Phone Number:** |

## 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 |
| May 2022 | 2.0 | Amendments to authorised supply pathways | ODC |
| July 2023 | 3.0 | Amendments following updated fees and charges structure | ODC |
| January 2023 | 4.0 | Amendments to Section 2.2 - Variation type | ODC |