

# Application to vary a Medicinal Cannabis Permit – Manufacture 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 manufacture of a cannabis drug for medicinal and scientific purposes, for one or more permitted supplies, 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: <a href="mailto:mcs.application@health.gov.au">mcs.application@health.gov.au</a>

۱.	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 site (e.g. no changes to fences, additional vaults or security changes) or activity since you last applied for a permit, or a licence variation has been approved prior to submitting this permit application.
	<b>Note:</b> 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

Fu	urther 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)?
	<b>Note</b> : 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
Fu	urther comments (if required):

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

### 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 manufacture of a cannabis drug for one or more permitted supplies.

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 <a href="mailto:MCS.application@health.gov.au">MCS.application@health.gov.au</a>

### 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 <a href="https://www.health.gov.au">www.health.gov.au</a>

### **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 ho	older name								
Licence nu	ımber								
Section 1	.2 - Applicatior	n contacts	ontacts			I have been nominated as the application contact: (select one option only)			
Application	on Contact #1								
First Name		Su	Surname		As I am an authorised persor	dec	have been clared as a minated contact by		
Phone Number		Er	mail Address	listed on the licence	the	the application signatory			
Application	on Contact #2								
First Nam	е		Surname			As I am an authorised person	dec	As I have been declared as a nominated contact by the application signatory	
Phone Number				mail Address	listed on the licence	the			
Section 1	.3 - Permit site	details							
Provide de	Provide details of the licensed premises at which authorised activities will be undertaken.								
Address	Street Number		Street						
Details	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 <a href="https://www.odc.gov.au">www.odc.gov.au</a> for current fee information.

Section 2.1 - Details of the current manufacture 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 (Complete Sections 3, 4 and 10 of this form)					
Туре Т		Change to maximum quantities held at any one time - without increasing total authorised quantities within the current permit period (Complete Sections 3, 7, 9 and 10 of this form)					
Type 2		Variation to authorised supply pathway categories - add or remove supply pathway(s)  (Complete Sections 3, 5, 8, 9 and 10 of this form)					
Type 3		Change to total authorised quantities within the current permit period  (Complete Sections 3, 7, 9 and 10 of this form)					
Туре 3		Variation to authorised manufacture activities (Complete Sections 3, 5, 6, 9 and 10 of this form)					

# Section 3 - Overview of variation application

# Section 3.1 - Scope and purpose of variation Please provide a brief overview of the particular aspects of the manufacture permit you wish to vary. This should include: The reasons why the variation is being sought, as well as justification for any relevant changes or increase in quantities (for example: a licence variation has occurred, changes in manufacture schedule, obtained starting material/manufacture quantities required to be increased). Explanation of the quantities proposed to be obtained and manufactured. Method of manufacture, storage and details of how end product will be supplied. Additional comments for 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 – Relevant licences issued by State/Territory (or other Commonwealth agency)

### Section 5.1 - Other licences

If applicable, please provide copies of relevant licences issued by State/Territory or other Commonwealth agencies.

If any relevant associated licences have been renewed/updated during this permit variation application, please attach copies of the relevant renewed/updated licences (if available) or provide further information.

Relevant State/Territory licences allow activities such as, (but not limited to) carry on business as a manufacture chemist, possession, use and distribution of Schedule 4, Schedule 8, and Schedule 9 drugs in accordance with State/Territory legislation. Additionally, should you hold a Good Manufacturing Practice (GMP) licence, kindly provide the relevant licence details in table below.

**Note**: if the licence holder has any other relevant information provided by the relevant State/Territory or Commonwealth agency, please attach evidence of this with the application and provide any further comments below (for example: State/Territory licence is not required based on the proposed activities, supporting correspondence from relevant agency, licence renewal information, etc).

If you have more than 2 licences, provide further information in the additional comments Section 5.1 table below, as required.

Details of licence (File name, state/territory of issue, substances and activities included, substances and activities excluded)	Quantities authorised under this licence (if specified)	Licence Number	Expiry date

Additional comments (if required):

Section 5.1 - Other licences						

# Section 6 – Overview of activities for manufacture purposes

# Section 6.1 - Activity the licence holder intends to undertake on this manufacture permit

### 1. Select which manufacture activity the licence holder intends to vary

Manufacture may include when the plant or separated resin undergoes a processing step (e.g. including CO<sub>2</sub>, supercritical fluid extraction), refining and transformation of one drug into another drug and the isolation of cannabinoids from the extract of cannabis.

Please note: A medicinal cannabis licence that authorises manufacture, granted under the *Narcotic Drugs Act 1967*, does not authorise the following activities: mixing cannabis extract with excipients, encapsulating or tableting, manufacturing quality, the manufacture of an active pharmaceutical ingredient (API), the manufacture of a preparation, processing, assembling, packaging, labelling, sterilisation, testing release of supply or testing in accordance with the Therapeutic Goods Order 93 (TGO93) requirements.

Please select activities to be added or removed (if applicable):		Manufacture activities
Add Remove		Solvent extraction (including CO <sub>2</sub> , supercritical fluid extraction) making an extract from cannabis or from cannabis resin of the cannabis flowers, cannabis resin or cannabis plant.
Add Remove		Isolation of cannabinoids from the extract of cannabis
Add	Remove	Refining the extract to obtain another drug, such as tetrahydrocannabinol (THC) or cannabidiol (CBD)
Add Remove  Add Remove		Converting or transforming cannabinoids into another drug
		Other - provide further information below (e.g. changes approved by a licence variation, etc)

Section 6.1 - Activity the licence holder intends to undertake on this manufacture permit								
Other comments:								

# Section 7 – Variation to authorised quantities

# Section 7.1 - Details for proposed variation to raw/starting material - Cannabis and/or cannabis extract

### 1. Provide details of proposed obtained starting material

### As relevant, these details should include:

- i. where the starting material is being obtained from;
- ii. how much starting material is being obtained over the life of the permit;
- iii. how much starting material you intend to hold at any one time;
- iv. how frequently the material is being delivered;

For consistency, please ensure that the cannabis starting materials are provided in the estimated dry weight (kg) (at 10% moisture content) as this is required to be recorded on permit.

Note: It is the responsibility of the licence holder under the Narcotic Drugs Act 1967 (the Act) to ensure that all parties conducting any medicinal cannabis activities also hold the applicable licences/permits authorised under Commonwealth, State or Territory legislation.

If you are receiving source materials from more than 4 entities, attach the completed schedule table as required.

Reference no.	Supplier	Source of starting material Imported or domestic	Source material type	Percentage of THC/CBD	Total amount required to be obtained over the life of the permit (kg)	Maximum amount held at any one time (kg)	How many batches of starting material will be received during the permit period?
			Note: if proposing lo	ower quantities, use section.	a negative (-) figure in this		
1							
2							
3							

Section 7.1 - De	tails for pro	posed variati	ion to raw/starti	ng material - C	annabis and/or ca	nnabis extract		
4								
Section 7.1 - De	etails for pro	posed variati	ion to raw/starti	ng material - c	annabis and/or ca	nnabis extract		
2. Supporting info	ormation for p	proposed cann	nabis source mater	ials				
These details sho	uld include:							
ii. confii iii. descr iv. descr v. wheti vi. suppo	<ul> <li>ii. confirm why the requirements have changed;</li> <li>iii. describe the delivery schedule of the starting materials;</li> <li>iv. describe the manufacture schedule of the starting materials;</li> <li>v. whether there is a standing order;</li> </ul>							
Reference no. (please use corresponding reference number, as above)  Supporting documentation attached (select yes or no)			ached Furth	er details				
1		Yes No - plea	se provide further	details				
2		☐ Yes ☐ No - please provide further details						
3		Yes No - plea	ise provide further	details				

Section 7.1 - Deta	ils for proposed varia	tion to raw/starting mate	rial - cannabis and/or c	annabis extract		
4	☐ Yes ☐ No - ple	ase provide further details				
Section 7.2 - Details for proposed variation to manufacture activities						
1. Proposed manufacture quantities of cannabis drugs at any one time						
		pture different types of cann components of the cannabis				ovtract
Licence holders und	der the <i>Narcotic Drugs A</i>	act 1967 (the Act) must adher reporting losses, record kee	re to all requirements app	lying to wholesalers in r	elation to the purchase,	
, and the second	•	anufacture activities, attach		•		
Reference no.  Complete details for each activity with the corresponding reference number for the raw/starting	Quantity of cannabis drug/s (kg) to be obtained from 1kg of starting material	Maximum amount of cannabis drugs (kg) to be held at any one time	Maximum extraction The sum of Delta-9 THC, the maximum amount o		) and CBD must equal	Will you, the licence holder, undertake further manufacture processes on this cannabis drug, to produce a cannabis drug in its final dosage form and pack type?

Delta-9 THC (kg)

Other THC (kg)

raw/starting material from

Section 7.1

2

Select yes or no

Yes ☐ No

Yes

☐ No

CBD (kg)

Section 7.2 - Deta	Section 7.2 - Details for proposed variation to manufacture activities						
3						☐ Yes ☐ No	
4						☐ Yes ☐ No	
Section 7.2 - Deta	Section 7.2 - Details for proposed variation to manufacture activities						
2. Proposed manuf	acture quantities of can	nabis drugs over the life of th	nis permit				
Reference no.  Complete details for each activity with the corresponding reference number for the raw/ starting material	Quantity of cannabis drug/s (kg) to be obtained from 1kg of starting material	Total quantity of cannabis drugs (kg) to be manufactured over the life of this permit	Total extracts to be The sum of Delta-9 THC, the total quantity of can of this permit	Will you, the licence holder, undertake further manufacture processes on this cannabis drug, to produce a cannabis drug in its final dosage form and pack type?			
from Section 7.1			Delta-9 THC (kg)	Other THC (kg)	CBD (kg)	Select yes or no	
1						☐ Yes ☐ No	

Section 7.2 - Details for proposed variation to manufacture activities						
2						☐ Yes ☐ No
3						☐ Yes ☐ No
4						☐ Yes ☐ No
Section 7.3 - Prop	osed varied permit So	hedule 1				
under the relevant		remises. Using your provided			ktract proposed be obtained our requested varied total qu	and authorised to be held uantities reflect your activities
Please review the d	rop-down options belov	v and:				
<ul> <li>select the tr</li> </ul>	ype of material that is b	eing varied in this application	n			
<ul><li>ensure that</li></ul>	the current permitted o	quantities are recorded below	w and provide the addition	nal (or changed)	) amounts required	
	·	ation is provided as an attach	·	· (g,	,	
	0	•				
Please note the sep	arate applicable rees fol	Type 1 and Type 3 variation	15.			
Тур	e of material	Qu	uantity to be changed		Current permitted quantities (kg)	Proposed quantities for the remainder of the permit period (kg)  Note: if proposing lower quantities, use a negative (-) figure in this section.

Section 7.3 - Proposed varied permit Schedule 1					

# Section 8 – Proposed varied permit – Schedule 2 overview

Sectio	Section 8 - Proposed variation to Supply pathways - Manufacture						
Supply	Supply Pathway items and requirements						
Item	Please select required response for each supply pathway	Supply pathway:  Please ensure any relevant options are selected	Licence holder requirements:  Please ensure any supporting documents are provided	Provide a brief description on any changes in the space provided below:			
1	Proposed Remove	Supply to another person (recipient) The cannabis drug is registered goods for the purposes of the <i>Therapeutic Goods Act 1989</i>	If the licence holder intends to supply a cannabis drug to a sponsor of a registered good for the purposes of the <i>Therapeutic Goods Act 1989</i> .  - Evidence of the registered good on the Australian Register of Therapeutic Goods (ARTG number).  - The licence holder must make and keep a record of the ARTG number relevant to the registered goods.				
2	☐ Proposed ☐ Remove	Supply to another person (recipient) The recipient holds a medicinal cannabis licence granted under the Narcotic Drugs Act 1967 which authorises the manufacture of a cannabis drug	If the licence holder intends to supply a cannabis drug to another holder of a medicinal cannabis licence which authorises manufacture under the Narcotic Drugs Act 1967 for purposes under this Act.  - Provide name of licence holder  - The licence holder must make and keep a record of the name of the recipient.  - Please ensure that any supporting documents are provided.				

Sectio	ection 8 - Proposed variation to Supply pathways - Manufacture				
3	Proposed Remove	Supply to another person (recipient) The supply of the cannabis drug is in accordance with an approval or authority under the <i>Therapeutic Goods Act 1989</i>	If the licence holder intends to supply a cannabis drug is in accordance with an approval or authority under the <i>Therapeutic Goods Act 1989</i> (e.g. Special Access Scheme (SAS) or Authorised Prescriber (AP)).  The licence holder must make and keep a record of the name of the recipient.  Please ensure that any supporting documents are provided.		
4	Proposed Remove	Supply to another person (recipient) The recipient holds a licence under Part 3-3 of the <i>Therapeutic Goods Act</i> 1989, and the cannabis drug 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 drug for manufacture to a holder of a Good Manufacturing Practice (GMP) licence for a purpose under the <i>Therapeutic Goods Act 1989.</i> - The licence holder must make and keep a record of the name of the recipient.  - Please ensure that any supporting documents are provided (e.g. GMP licence/number)		

Sectio	Section 8 - Proposed variation to Supply pathways - Manufacture					
5	Proposed Remove	Supply by way of export The licence holder has been issued an export licence and permission pursuant to the <i>Customs (Prohibited Exports) Regulations 1958</i>	If the licence holder intends to export a cannabis drug to an overseas entity in a country that has authorised the import of the cannabis drug.  The licence holder must make and keep a record of:  • the name of the importing country; and • the export licence number - Please ensure any supporting documents are provided.			
6	Proposed Remove	Supply to another person (recipient) The cannabis drug is supplied for use by a pharmacist in a public hospital for the purposes of that pharmacist dispensing the drug in accordance with the <i>Therapeutic Goods Act 1989</i>	If the licence holder intends to supply to a public hospital pharmacist dispensing the drug in accordance with the <i>Therapeutic Goods Act 1989</i> .  The licence holder must make and keep a record of the name of the hospital and the responsible pharmacist.  The licence holder must ensure that supply is only to a pharmacist in a public hospital.  Please ensure any supporting documents are provided.			
7	Proposed Remove	Supply to another person (recipient) The cannabis drug is supplied for use as a reference standard for medical or scientific testing purposes	The licence holder intends to supply a cannabis drug as a reference standard for medical or scientific testing purposes.  The licence holder must make and keep a record of the name of the recipient.			

Section	Section 8 - Proposed variation to Supply pathways - Manufacture					
			- Please ensure any supporting documents are provided.			
8	Proposed Remove	Supply to another person (recipient) 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 <i>Therapeutic Goods Act</i> 1989	If the licence holder intends to supply a cannabis drug for use in a clinical trial.  The licence holder must make and keep a record of the CTA or CTN number.  Please ensure any supporting documents are provided.			
9	☐ Proposed ☐ Remove	Supply to another person (recipient) The cannabis drug is supplied for use in medical or scientific research which:  (i) is not a clinical trial that is, or is likely to be, approved (CTA) or notified (CTN) under the <i>Therapeutic Goods Act 1989</i> ; and  (ii) does not involve the drug being administered to humans	If the licence holder intends on supplying cannabis drugs for medical or scientific research not intended for a clinical trial or use in humans.  - The licence holder must obtain, and keep a record of, the details of the research project and the manner in which the cannabis drug is to be used.  - Please ensure any supporting documents are provided.			
10	Proposed Remove	Supply for the purposes of an extemporaneously-compounded medicinal cannabis product (recipient)  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	If the licence holder intends on supplying a cannabis drug to a recipient who intends to supply an extemporaneously-compounded medicinal cannabis product in accordance with the <i>Therapeutic Goods Act 1989</i> (e.g. to a compound pharmacist).			

Section 8 - Proposed variation to Supply pathways - Manufacture					
	Goods Regulations 1990) in accordance with the <i>Therapeutic Goods Act 1989.</i>	<ul> <li>The licence holder must make and keep a record of the name of the recipient.</li> <li>The licence holder must provide the relevant business address and at least one Healthcare Provider Identifier.</li> <li>The licence holder must ensure that supply is only to patients under the Special Access Scheme (SAS) or Authorised Prescriber (AP).</li> <li>Please ensure any supporting documents are provided.</li> </ul>			

# Section 9 – 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 10 – 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;
- b. I declare that, to the best of my knowledge, this form is complete and all relevant information has been provided;
- c. I have read guidance document "Guidance: Applying for a medicinal cannabis permit for medicinal or scientific purposes Manufacture activities" in addition to completing this application;
- 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;
- e. 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: insert in	nage 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 2024	4.0	Amendment to Preliminary Question 1 and Section 2.2 - Variation type	ODC