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

The cultivation and production of cannabis, for medicinal or scientific purposes in accordance with the *Narcotic Drugs Act 1967*.

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

Screening questions

1. Is an active permit currently held authorising the cultivation and production of cannabis drugs under the *Narcotic Drugs Act 1967*?
   - ☐ **Yes**
   - ☐ **No**
2. Does the permit that this application seeks to vary have a period of greater than 3 months until the expiry date?
   - ☐ **Yes**
   - ☐ **No**
3. 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 (ODC) for next steps.

Part 1 – General details

1. Licence holder details						
Licence holder name						
Permit number				Permit expiry date		
Person(s) authorised to discuss the variation with the ODC, if different to approved contacts	Name		Phone		Email	
	Name		Phone		Email	

2. Licensed premises details for this permit						
Address	Street					
	Town/ Suburb		State		Postcode	

Part 2 - Variation type

Please select the applicable option/s below that correspond to the type of variation that is being applied for. Please note that Minor and Major variation types attract different fees, see the ODC website for current fee information:

☐ Reduction in the size of a crop to be cultivated *(minor variation)*	☐ Variation to authorised cultivation and production activities *(major variation)*
☐ Increase in maximum quantity of low THC with no change to total authorised quantity *(minor variation)*	☐ Variation to authorised supply pathway categories *(major variation)*
☐ Increase in maximum quantities within the current permit period *(major variation)*	☐ Other (please specify in Part 3 and/or 4)

Part 3 - Existing cannabis material (*held at time of variation application*)

Is this application to increase or decrease maximum quantities?	☐ Yes ☐ No *If yes, complete this section*

Type of cannabis material		**Estimated maximum quantity (*total units*) in possession or control of the licence holder at the time of application.**	**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 4 – Variation details

Scope and purpose of variation
Provide details of the particular aspects of the cultivation and production permit the licence holder wishes to vary. Include the reasoning why the variation is being sought, as well as justification for any relevant increase in quantities (for example higher plant density or shorter crop cycles). ***Note:*** *Include a justification of the quantities proposed in parts 5 and 6 below. If applicable, 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), as well as estimated crop cycles/ batches for intended cultivation and production across the twelve-month permit period.* ***Note****: If the licence holder intends to undertake activities relating to tissue culture, please provide details such as growth mediums, storage methods and use of tissue culture. Tissue culture related activities must not be prohibited by the conditions of the licence; if they are, a licence variation will be required to vary those conditions.*

Part 5 – Variation to cultivation and production activities

Is this section applicable to the variation?	☐ Yes	☐ No

Select which activity(s) the licence holder intends to vary 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.

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*.

Select which activity(s) the licence holder intends to vary under this permit

Part 6 – Quantities to be varied

Please use the drop-down options to select the type of material the applicant intends to vary and the quantity to be changed. Add the new total of the intended varied plant material and altered quantities in 'Part 6' of the application form.

Is this section applicable to the variation?	☐Yes	☐ No

Type of plant material	Quantity to be changed	Type	Current quantity permitted on the permit	Additional quantity the licence holder wishes to add to the total quantity *Note: Please add the new intended total in 'Part 6' below. If proposing lower totals, use a negative number in this section.*
Choose an item. Seeds	Choose an item. Units to be obtained from othe	**Low THC**		
		High THC		
Choose an item. Seeds	Choose an item. Units to be obtained from othe	**Low THC**		
		High THC		
Choose an item. Seeds	Choose an item. Units to be obtained from othe	**Low THC**		
		High THC		
Choose an item. Seeds	Choose an item. Units to be obtained from othe	**Low THC**		
		High THC		
Choose an item. Seeds	Choose an item. Units to be obtained from othe	**Low THC**		
		High THC		
Choose an item. Seeds	Choose an item. Units to be obtained from othe	**Low THC**		
		High THC		

Part 7– Permit details – New proposed schedules for cultivation and production activities.

From the information provided in the above sections, fill in the new proposed quantities for the requested varied permit.

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

Note: *permit variations must be approved by the Delegate of the Secretary before any activities on new proposed quantities can be performed.*

			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***		

**For this purpose, a plant unit is one that has formed roots*

			Quantity	
			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 8 – Variation to Supply Pathway Categories

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 attach copies of any relevant contracts or documents to support this application.

Is this section applicable to the variation?	☐ Yes	☒ No

Cannabis or cannabis resin supply pathways		
	Supply pathway *Tick the box/s that the licence holder intends on supplying only*	Provide a description below of how the licence holder intends to supply under each supply pathway selected: · **Supply to *Narcotic Drugs Act 1967* licenced manufacturer –** Name of licence holder · **Supply to *Therapeutic Goods Act 1989* licensed manufacturer -** Name of licence holder · **Testing or research –** Details of project · **Supply to recipient under state and territory legislation –** Name of licence holder · **Export –** The overseas importing country and *Customs Prohibited Export Regulations1956* Export licence number (if currently available) · **Pharmacist or public hospital –** name of recipient · **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 premise (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 for the purposes of the recipient supplying extemporaneously-compounded medicinal cannabis products in accordance with the *Therapeutic Goods Act 1989*	

Part 9 – Declaration

Declaration	
I declare that, to the best of my knowledge, all the information in this application is true and correct. I am aware that giving false or misleading information is a serious offence—see Division 136 and 137 of the *Criminal Code Act 1995,* and I have read the guidance document "Applying for a medicinal cannabis permit for medicinal or scientific purposes – Cultivation and production activities" before completing this application. I declare that, to the best of my knowledge, my application is complete and all relevant documentation has been provided. I acknowledge that providing incomplete or out of date documentation may result in processing and assessment delays for my application.	
Signature:	
Name:	**Date:**
Direct contact number:	**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