Australian Government
Department of Health
Office of Drug Control

This form, when completed, will be classified as
'Unclassified: For Official Use Only'

Application to vary a Medicinal Cannabis Permit – Manufacture for medicinal or scientific purposes.

The manufacture of cannabis or cannabis resin, 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 manufacture of cannabis drugs under the *Narcotic Drugs Act 1967*?
2. Does the permit this application seeks to vary have a period of greater than 3 months until the expiry date?
3. Is the area where this activity will be undertaken accurately reflected on the site and floor plant referenced on the medicinal cannabis licence?

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

Select the applicable option/s below that correspond to the type of variation that is being applied for. Note that minor and major variations attract different fees, see the ODC website for current fee information:

☐ Reduce maximum quantities within the current permit period *(minor variation)*	☐ Change in manufacture activity *(major variation)*
☐ Increase maximum quantities within the current permit period *(major variation)*	☐ Change in authorised supply pathway categories *(major variation)*
☐ Change of starting material *(major variation)*	☐ Other (please specify in Part 4)

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

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

Type of cannabis material	Estimated maximum quantity still in possession or control of the licence holder at the time of application	Comments
Manufactured material – delta 9 THC extract (kg)		
Manufactured material – other THC extract (kg) **(other THC cannabinoids excluding delta-9 THC and CBD)**		
Manufactured material – CBD extract (kg)		
Starting material – cannabis extract (kg)		
Starting material – Dried cannabis and resin (kg)		
Other (describe in comments)		

Part 4 – Variation details

Scope and purpose of variation
Provide details of the particular aspects of the manufacture 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, additional contracts have been entered into) ***Note:*** *If applicable**,** include a justification of the varied quantities proposed in parts 5 and 6 below. Include method of manufacture, storage, and details of how the end will be manufactured (i.e. starting material, cannabis resin, and purpose of supply/ retention) if this is different from activities already approved.*

Part 5 – Variation of activities for manufacture purposes

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

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

☐ Solvent extraction (including CO2, supercritical fluid extraction) making an **extract** (including tinctures) from cannabis or from cannabis resin of the cannabis flowers, cannabis resin or cannabis plant.

☐ Isolation of cannabinoids from the extract of cannabis

☐ Refining the extract to obtain another drug, such as Tetrahydrocannabinol (THC) or Cannabidiol (CBD)

☐ Converting or transforming cannabinoids into another drug

☐ Other – (provide details)

Provide details of the varied activities intended to be undertaken under the current manufacture permit.

Note: *A medicinal cannabis licence that authorises manufacture does not cover the following activities if undertaken in isolation: dilution of an extract, mixing an extract with excipients, encapsulating or tableting, manufacturing quality, the manufacture of an active pharmaceutical ingredient (API), the manufacture of a preparation, production (processing, assembling, packaging, labelling, storage, sterilisation, testing release of supply), and Therapeutic Goods Order 93 (TGO93) requirements.*

Part 6 – Quantities to be varied

Use the drop-down options to select the type of manufacture activity the licence holder intends to vary and the quantity category to be changed. Add the new total of the intended varied plant material and altered quantities in 'Part 8' of the application form.

For examples on how to calculate cannabinoid (THC/CBD) concentrations for manufacture activities, see page 10 in the guidance material for 'Applying for a medicinal cannabis permit for medicinal or scientific purposes – Manufacture activities'

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

	Type of manufacture activity ***Use drop down box for options***	**Quantity category to be changed** ***Use drop down box for options***	**Strength/concentration of THC & CBD to be manufactured (if applicable)**		**Current quantity permitted on the permit**	**Additional quantity the licence holder wishes to add to the total quantity** *Note: Add the new intended total in 'Part 8' below*
			THC g/kg	**CBD g/kg**		
1	Choose an item.	Choose an item.				
2	Choose an item.	Choose an item.				
3	Choose an item.	Choose an item.				
4	Choose an item.	Choose an item.				

Part 7 –Variation to Manufacture activities

If the licence holder intends on varying the drugs to be manufactured under the current permit, complete the below table

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

Variation to manufacture activities							
Ref. *Complete details for each activity with the corresponding reference number for the 'starting material', or 'drugs to be manufactured' options from 'Part 6' of the application*	Quantity of cannabis drug/s (kg) to be obtained from 1kg of *additional** starting material **additional starting material refers to the quantity of cannabis material requesting to be varied*	Total quantity of cannabis drugs (kg) to be manufactured	Extracts to be manufactured *This should include the proposed cannabis material to be added to the permit.*			*New proposed* maximum amount of cannabis drugs (kg) to be held at any one time	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)	Non-Delta 9 THC (kg)	CBD (kg)		
example 1	*0.5kg/kg*	*25kg*	*2.5kg*	*2.5kg*	*20kg*	*25kg*	*Tick box*
1							☐ **Yes** ☐ **No**
2							☐ **Yes** ☐ **No**
3							☐ **Yes** ☐ **No**

Part 8: Permit details - New proposed Schedules for Manufacture Activities

From in the information provided in the above sections, fill in the new proposed quantities to be varied on the current permit.

Types and quantities of medicinal cannabis proposed be manufactured under the relevant licence at this premises:

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

			Quantity
Raw/Starting material	Cannabis	*Total quantity of cannabis proposed to be **obtained** over the life of this permit (kg) **(dry weight at 10% moisture content)***	
		*Maximum quantity of cannabis proposed to be onsite at **any one time** (kg) **(dry weight at 10% moisture content)***	
	Cannabis extract	*Total quantity of cannabis extract proposed to be **obtained** over the life of this permit (kg)*	
		*Maximum quantity of cannabis extract proposed to be onsite at **any one time** (kg)*	

			Quantity
Manufacture activities	Drugs manufactured from cannabis under this permit	*Total quantity of delta-9 tetrahyrdocannabinols (THC) **proposed to be manufactured** (kg)*	
		*Maximum amount of delta-9 THC **proposed on the premises** at any one time (kg)*	
		*Total quantity of non-delta-9 THC (THC Isomers other than delta-9 THC) **proposed to be manufactured** onsite (kg)*	
		*Maximum amount of non-delta-9 THC (THC Isomers other than delta-9 THC) **proposed to be on the premises** at any one time (kg)*	
		*Maximum amount of cannabidiol (CBD) **proposed to be manufactured** on site (kg)*	
		*Maximum amount of CBD **proposed to be on the premises** at any one time (kg)*	

Part 9 – Variation to Supply Pathway Categories

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 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 adding to the permit's supplying categories.*	Provide a description of how the licence holder intends to supply under each supply pathway selected in the space provided below: • **Clinical trial** – CTN/CTA number • **Research –** Details of research project • **Export –** The overseas importing country and *Customs Prohibited Export Regulations 1956* Export licence number (if currently available) • **Supply to *Therapeutic Goods Act 1989* licenced manufacturer -** Name of licence holder • **Registered Goods** – ARTG number • **Public hospital pharmacist –** name of hospital pharmacy • **Supply to the holder of a licence authorising manufacture under the *Narcotic Drugs Act 1967*–** Name of licence holder • **Supply for use as a reference standard for medical or scientific testing purposes** – name of recipient • **Supply under the *Therapeutic Goods Act 1989* -** How will the licence holder ensure that supply is in accordance with an approval or authority under the TG Act?
1	☐ Registered goods for the purposes of the *Therapeutic Goods Act 1989*	
2	☐ Supply to the holder of a licence authorising manufacture 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 under the *Therapeutic Good Act 1989*	
5	☐ Export	
6	☐ Supply to a pharmacist in public hospital	
7	☐ Reference standard	

8	☐ Supply for the use in a clinical trial	
9	☐ Supply for use in medical or scientific research	

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 – Manufacture activities" before completing this application. I declare that, to the best of my knowledge, the 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 the 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