Australian Government
Department of Health
Office of Drug Control

Application for a permit to manufacture narcotic drugs from cannabis and/or cannabis resin

Before starting your application

This form can be used by the holder of a manufacture licence under the *Narcotic Drugs Act 1967* to apply for a permit in relation to activities that are authorised by the licence.

Fees

The fee for an application for a medicinal cannabis manufacture permit, is AUD $3,440.

Payment is required upon receipt of an invoice from the Australian Government Department of Health. Note that the application fee is non-refundable.

Providing incorrect information

It is a serious offence for a person to knowingly make a false or misleading statement in relation to an application – see Division 136 and 137 of the *Criminal Code Act 1995*. Significant fines apply.

Privacy

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

After you lodge your application

The lodgment of an application for a permit under the *Narcotic Drugs Act 1967* **does not** constitute approval to commence or continue activities that may be authorised under such a permit. Such actions may be unlawful.

ODC may request additional information or documents to supplement the contents of a lodged application in order to reach a decision.

1. Licence holder information
1.1 Name of licence holder:
1.2 Manufacture licence number:

2. Declaration and consent
I hereby apply to the Secretary, Department of Health, for a permit to manufacture narcotic drugs (derived from cannabis or cannabis resin). I declare that, to the best of my knowledge, all the information in this application is true, correct and complete. I am aware that giving false or misleading information is a serious offence—see Division 136 and 137 of the *Criminal Code Act 1995*. In addition, the Secretary is required to refuse to grant a manufacture permit, if the Secretary is satisfied on reasonable grounds that the application contains information, or information has been given in relation to the application that is false or misleading in a material particular, or omits matters or things without which the application is misleading in a material respect. It is also a ground for revocation if the permit was obtained or varied on the basis of information described above.

Signature of authorised person:	**Name:**
	Date:
	Email:
	Direct contact number:

3. Summary of permit request

Please provide an overview of what manufacture activities you would like to be permitted to do:

Do you currently hold a permit related to this licence? Yes / No

Permit no: Expiry date:

If yes, please estimate the maximum quantities you will hold under this permit on the expiry date

Cannabis extract (kg):

Starting material (kg):

Decisions to grant or refuse permits will rely on the information you provide in the schedules below.

SCHEDULE 1 State/Territory licences

Attach copies of relevant state/territory licences you currently hold

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.

Note, if you have been advised by the relevant state/territory agency that a state/territory licence is not required based on the proposed activities, attach evidence of this with your application.

File name

File name

Details of licence (state/territory issued by, substances and activities included, substances and activities excluded)	**Licence No.**	**Expiry date**

If you have more than 2 state/territory licences, attach separate sheets labelled appropriately.

SCHEDULE 2 Starting materials

Describe the supply arrangements for starting material. ***(I.e. Do you have a standing order? What frequency do you receive starting material? How is this frequency determined?):***

Ref.	Supplier/producer	Source of stating material (Imported or domestic)	Source material type	Strength/concentration of THC/CBD	Amount required (kg)	Maximum amount held at any time (kg)	Expected supply date MM/YYYY
eg 1	*eg Company name*	*Imported*	*Dried cannabis (High CBD, Low THC)*	*10-15% CBD, 1-2% THC)*	*12*	*2*	*June 2020*
eg 2	*eg Company name*	*Domestic*	*Cannabis resin (High THC)*	*15-20% THC, <1% CBD*	*2,500*	*500*	*July 2020*
1							
2							
3							
4							

SCHEDULE 3 Manufacture activities

Proposed permit start date DD/MM/YYYY	**Proposed permit finish date** DD/MM/YYYY

Ref. *Complete details for each activity with the corresponding reference number for the starting material from Schedule 2*	**Quantity of cannabis extract (kg) to be obtained from 1kg of starting material**	**Total quantity of cannabis extract (kg) to be manufactured**	**Strength/concentration of THC & CBD in the extract (g/kg)**		**Proposed manufacture start date** **MM/YYYY**	**Proposed manufacture finish date** **MM/YYYY**	**Maximum amount of extract (kg) held at any time**	***Will you, the licence holder, undertake further manufacture processes on this cannabis extract, to produce a medicinal cannabis product in its final dosage form and pack type?***
			THC g/kg	**CBD g/kg**				
eg 1	*0.5kg/kg*	*25kg*	600g/kg	20g/kg	*Sept.2020*	*Dec.2020*	*25*	*Tick box*
1								☐ **Yes –** Complete schedules 4 & 5 ☐ **No –** Complete schedule 4
2								☐ **Yes –** Complete schedules 4 & 5 ☐ **No –** Complete schedule 4
3								☐ **Yes –** Complete schedules 4 & 5 ☐ **No –** Complete schedule 4
4								☐ **Yes –** Complete schedules 4 & 5 ☐ **No –** Complete schedule 4

If you propose to carry out more than 4 manufacture activities, attach separate sheets labelled appropriately.

SCHEDULE 4 Supply pathway		
Ref. *Complete details for all drugs with the corresponding reference number from Schedule 3 page 4.* *eg 1&2*	**Supply pathway** *Please tick the box/s that you intend on supplying only*	**Provide the corresponding information based on your supply pathway (listed below):** • **Clinical trial** – CTN/CTA number • **Research –** Details of research project • **Export –** The overseas importing country and *Customs Prohibited Export Regulations1956* Export licence number (if currently available) • **Supply to Therapeutic Goods Act 1989 licensed manufacturer -** Name of licence holder • **Registered Product** – ARTG number • **Public hospital pharmacy –** name of hospital pharmacy • **Supply to Narcotic Drugs Act 1967 licenced manufacturer –** Name of licence holder • **Supply under the Therapeutic Goods Act 1989 -** How will you ensure that supply is only to patients under the Special Access Scheme or an Authorised Prescriber?
	☐ Clinical trial ☐ Registered product ☐ Research ☐ Supply under the *Therapeutic Goods Act 1989* ☐ Supply to a public hospital pharmacy ☐ Export ☐ Supply to the holder of a manufacture licence under the *Narcotic Drugs Act 1967* ☐ Supply to the holder of a licence under part 3-3 of the *Therapeutic Goods Act 1989*	

If you propose to manufacture more than one drug, attach separate sheets labelled appropriately.

SCHEDULE 5 Medicinal cannabis product

Ref. *Complete details for all drugs with the corresponding reference number from Schedule 4 page 5.* *eg. 1*	**Drug to be manufactured**	**Strength/concentration of THC and CBD**		**Unit description**	**Total quantity to be manufactured**	**Proposed manufacture start date** MM/YYYY	**Proposed manufacture finish date** MM/YYYY	**Maximum amount held at any time**
		THC mg/mL	CBD mg/mL					
eg 1	*Cannabis extract (CBD:THC 1:1)*	25mg/mL	5mg/mL	*10mL vial*	*1000 vials*	*Sept.2020*	*Dec.2020*	*200 vials*
eg 2	*Cannabis extract (THC)*	30mg/mL	-	*5mg capsule*	*500 capsules*	*Nov. 2020*	*Feb. 2021*	*100 capsules*
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

If you propose to manufacture more than 10 medicinal cannabis products, attach separate sheets labelled appropriately.