



SECTION 4 Licence module – Manufacture Licence for narcotic drugs

The manufacture of narcotic drugs for medicinal and related scientific purposes in accordance with the *Narcotic Drugs Act 1967*.

Important notice

Complete this licence module if it is applicable to your application. The completed module must be attached and submitted along with all other parts in order to form a complete application.

Information required

This module requests information relating to the type of licence and subsequent range of authorised activities for which approval is sought.

4.1 Application type (Check one box for each type of licence)

Licence to manufacture:

- New application
- Renewal

Manufacturing activities

'Manufacture' means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.

4.2 Summary of manufacturing activities

- Transport of drugs
- Storage of drugs
- Possession and control of drugs
- Disposal or destruction of drugs
- Extraction of cannabis and/or cannabis resin
- Processing, purification of cannabis extracts
- Supply of drugs
- Manufacture of drugs other than from cannabis
- Export of drugs
- Packaging of drugs into final product
- Research (provide details in the research section)
- Laboratory analysis of cannabis, cannabis resin, extracts, drugs, manufactured products
- Other activities (summarise in 4.12)

4.3 Provide details of the activities proposed to be undertaken under a licence, including details of the activities indicated in the summary at 4.2.

If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.

4.4 Is the drug proposed to be manufactured, a medicinal cannabis product?

No Yes - Complete [Manufacturing Schedule 1](#)

If No, provide details of:

4.4a the drug(s) to be manufactured.

If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.

4.4b the proposed end use of the manufactured drug(s).

If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.

Research

4.5 Does the research relate to medicinal cannabis products? <input type="checkbox"/> No – Go to 4.9 <input type="checkbox"/> Yes
4.6 Provide details of the research proposed to be carried out and the purpose of such research. If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.
4.7 Provide details of the financial resources and other resources that will enable the applicant to carry out such research. If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.

4.8 Provide details of the qualifications and expertise of the persons employed or engaged by the applicant to carry out such research.

If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.

Medicinal cannabis product

4.9 Is the drug a medicinal cannabis product that will be supplied to clinical trials or the public?

No – Go to 4.12 Yes

4.10 Will the product be used in a clinical trial? No Yes

4.10a If yes, provide details of the clinical trial in which the product will be used.

4.11 Will the product be supplied to the public? No Yes

4.11a If yes, provide details of the authority or approval under the *Therapeutic Goods Act 1989* under which supply is to occur.

Other activities (other than research and manufacture)

4.12 Summarise other activities.

If you need more space to clearly answer this question, attach a separate sheet labelled appropriately.

State / Territory Government licence(s)

4.13 Attach copies of relevant licences (if available) or specify state / territory licences required

Details of licence (state / territory issued by, substances covered, substances excluded)	Licence No (if available)	Expiry date (if available)

If you selected Yes at 4.4, complete the Manufacturing Schedule 1 on the next page, otherwise continue to and complete SECTION 5

Manufacturing Schedule 1 – Manufacturing activities (specific to cannabis and cannabis resin)

4.14 Complete this table for extraction of cannabis and/or cannabis resin

Note: This information assists the Drug Control Section (DCS) in establishing estimates for Australia’s licit drug requirements as required under United Nations agreements. The information also allows DCS to check that manufacturers hold appropriate State / Territory licences for drugs that they manufacture in the calendar year. This reduces delays when permit applications are lodged. The information provided does not authorise the import or export of any quantity of drug by a licensed importer or exporter. International quotas are a relevant consideration when issuing permits for the import / export of specific consignments.

Ref	Calendar year	Drug to be manufactured	Strength/Concentration Cannabinoids (THC/CBD)	Unit description	Number of units required annually	Total volume to be manufactured	Cannabis required for extraction
	e.g. 2017	e.g. Cannabis extract (CBD:THC 1:1)	15mg/mL CBD, 15mg/ml THC	10mL vial	10,000	100L	700 kg
	e.g. 2017	e.g. Cannabis extract (THC)	5mg/mL	Capsule	70,000	100L	700 kg
	e.g. 2017	e.g. cannabis extract (CBD:THC 1:1)	15mg/mL CBD, 15mg/ml THC	Kilogram	95 kg	100L	700 kg
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Continue to and complete SECTION 5