



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

The manufacture of narcotic drugs, derived from cannabis, for medicinal and related scientific purposes in accordance with the [Narcotic Drugs Act 1967](#).

| 1. Application type (check one box for each type of licence) | | | |
|--|--|-----------------------------------|--|
| Application type: | <input type="checkbox"/> Commercial | <input type="checkbox"/> Research | |
| Licence to manufacture: | <input type="checkbox"/> New application | <input type="checkbox"/> Renewal | |

| 2. Application details | |
|----------------------------|----------------|
| Name: | |
| Position held: | Mobile number: |
| Direct phone number: | Contact email: |
| Out of hours phone number: | |

| 3. Business information | |
|--|----------------------|
| Name of business/company / organisation: | |
| ABN / ACN: | |
| Site phone number: | |
| Site street address: | Site postal address: |

4. Manufacturing Activities

Summary of manufacturing activities

- | | |
|--|---|
| <input type="checkbox"/> Extraction of cannabis and/or cannabis Resin | <input type="checkbox"/> Packaging of manufactured product into final product |
| <input type="checkbox"/> Processing, purification of cannabis extracts | <input type="checkbox"/> Export of manufactured product |
| <input type="checkbox"/> Supply of manufactured product to other party | <input type="checkbox"/> Laboratory analysis of cannabis, cannabis resin, extracts, manufactured products |
| <input type="checkbox"/> Research (summarise in the research section) | <input type="checkbox"/> <i>Other activities</i> (summarise in next section) |

Research

Summarise research

Other activities

Summarise *other activities*

Drugs and products to be manufactured

Schedule 3 must be completed for each drug/product

5. Transport

| Name | Address | Service provided |
|------|---------|------------------|
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| 6. State/Territory Government licence(s) | | |
|---|------------|-------------|
| Please 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 | Expiry date |
| | | |
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| 7. Fit and proper person requirements | | |
|--|---------------|--------------------------------|
| Required for each business owner (ABN) and owners, officer holders (e.g. Directors) (ACN), persons with a financial interest and persons with decision making powers or influence. | | |
| Schedule 1 must be completed for each person | | |
| Full name | Position held | Phone number and email address |
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8. Proposed Senior Person in Charge
Schedule 2 must be completed by each nominated person

The applicant must nominate a senior person in charge (and deputy's) for the site.
The Senior Person in Charge must be either Directors of the Company, Business owner or employees.
Contact by the licensee to this office will only be accepted from persons who are confirmed as the Senior Person in Charge or their deputy's for a specified licence.

| Employee's full name | Position held | Phone number and email address |
|----------------------|---------------|--------------------------------|
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9. Declaration and consent

I hereby apply to the Secretary, Department of Health, for a licence to manufacture narcotic drugs (derived from cannabis).

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*.

I understand that it is standard practice for the Office of Drug Control, of the Department of Health, to provide any or all of the contents of this application, including personal information as defined in the *Privacy Act 1988*, to law enforcement agencies and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure laws and regulations are being complied with. I consent to all such disclosures and associated exchanges of information, including specifically personal information about me.

Signature of applicant:

| | |
|--------------|--------------|
| Name: | Date: |
|--------------|--------------|

Total number of pages in this application:

Schedule 1 – Fit and proper requirements

Full name:

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Date of birth:

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Company name:

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Identification

Provide three certified true copies of identification which includes at least one Category A.

Category A:

| | |
|---|--|
| <input type="checkbox"/> Birth certificate | <input type="checkbox"/> Australian passport |
| <input type="checkbox"/> Australian citizenship certificate | <input type="checkbox"/> Foreign passport |

Category B:

| | |
|--|--|
| <input type="checkbox"/> Drivers licence (with photo) | <input type="checkbox"/> Medicare card |
| <input type="checkbox"/> Evidence under the <i>Migration Act 1958</i> of permanent residence | |

Previous names:
(if applicable)

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Position held in
company:

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Contact phone No.:

| | |
|--|-----------------------|
| | Contact email: |
|--|-----------------------|

Current residential
street address:

| House No. and street name | Suburb / town | State | Postcode |
|---------------------------|---------------|-------|----------|
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Previous residential
street address
(within the last 5 years)

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National police
certificate attached

Original Certified copy Not provided - **last provided:**

Previous business
experience*:

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Convictions

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Civil penalties

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**Revocations,
suspensions relating
to
prohibition/regulation
of drugs**

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*Attach resume detailing previous business experience.

Declaration and consent

I declare that to the best of my knowledge all the information provided in this schedule 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*.

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Signature

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Date:

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Schedule 2 – Senior Person in Charge (and deputy’s)

(Please attach extra pages for each proposed senior person or deputy, as required.)

Applications for permits to manufacture are only accepted from, or discussed with, the **licence holder** or other persons who are confirmed as **the Senior Person in Charge (or their deputy)** for a specified licence.

| | | | | |
|---|---|----------------------|--------------|-----------------------|
| Applicant’s full name | | | | |
| Date of birth | | | | |
| Company name | | | | |
| Drivers licence No. | | | | |
| Previous names (if applicable) | | | | |
| Position held in company | | | | |
| Contact phone No. | | | | Contact email: |
| Current residential street address | House No. and street name | Suburb / town | State | Postcode |
| | | | | |
| Previous residential street address | | | | |
| National police certificate attached | <input type="checkbox"/> Original <input type="checkbox"/> Certified copy <input type="checkbox"/> Not provided - last provided: | | | |

Declaration and consent

I declare that to the best of my knowledge all the information provided in this schedule 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*.

I understand that it is standard practice for the Office of Drug Control, of the Department of Health, to provide any or all of the contents of this schedule, including personal information as defined in the *Privacy Act 1988* to law enforcement agencies and regulatory agencies in the Commonwealth, States and Territories as necessary, in order to ensure laws and regulations are being complied with. I consent to all such disclosures and associated exchanges of information, including specifically personal information about me.

| | | | |
|-----------------------------------|--|--------------|--|
| Signature of the applicant | <input style="width: 350px; height: 30px;" type="text"/> | Date: | <input style="width: 200px; height: 30px;" type="text"/> |
|-----------------------------------|--|--------------|--|

Schedule 3 – Manufacturing activities

| 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. 2016 | e.g. cannabis extract (CBD:THC 1:1) | 15mg/mL CDB, 15mg/ml THC | 10mL vial | 10000 | 100L | 700 kg |
| 2016 | e.g. cannabis extract (THC) | 5mg/mL | capsule | 70,000 | 100L | 700 kg |
| 2017 | e.g. Cannabis extract (CBD:THC 1:1) | 15mg/mL CDB, 15mg/ml THC | kilogram | 95 kg | 100L | 700 kg |
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Please 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 the 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.

**DOSSIER CHECKLIST
(APPLICANT TO COMPLETE)**

1. Drugs

| | |
|--|---|
| | Drugs to be manufactured |
| | End use of drugs |
| | Estimates for cannabis/cannabis resin to be used in manufacture |
| | Estimates of quantities of drug to be manufactured |
| | End user(s) of drug / manufactured product |
| | Research activities (if applicable) |

2. Manufacture

| | |
|--|--|
| | Manufacturing process |
| | Source(s) or raw materials to be used in manufacture |

3. Manufacturing facility

| | |
|--|--|
| | Site map |
| | Details of facilities |
| | Local planning laws/requirements – compliance |
| | Security and access details |
| | Disposal and destruction arrangements |
| | Supply and transport details |
| | State/Territory licences |
| | Arrangements with local authorities (emergencies, environmental contamination) |
| | Standard operating procedures |

4. Records

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|--|-----------------------------|
| | Record keeping arrangements |
|--|-----------------------------|

5. Staff

| | |
|--|------------------------------|
| | Staff details |
| | Access areas |
| | National police certificates |
| | Declarations |
| | Financial declaration |