Australian Government
Department of Health
Office of Drug Control

Guideline: Manufacture Licence

Manufacture of Drugs from *Cannabis*

Version 1.0, October 2016

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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
30 October 2016	1.0	Initial publication	ODC

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Introduction

This guideline is for *manufacture licences* **only**. If you are also intending to cultivate and produce cannabis and/or cannabis resin, refer to the application forms and guidance page of the Office of Drug Control (ODC) website.

This document is issued as guidance for persons who wish to make applications for licences or permits to manufacture narcotic drugs in accordance with the *Narcotic Drugs Act 1967* (ND Act).

NOTE: All applicants are subject to *fit and proper person requirements* (Section 8A and 8B of the ND Act*).*

The overall regulation of the licit narcotic manufacturing industry in Australia is a shared arrangement between the Australian Government and State and Territory Governments. While this guidance focuses on the Australian Government requirements and processes, an overview of the separate, but related arrangements under state/territory legislation is also provided for information.

Regulating national manufacture of narcotic drugs consistent with international obligations

As a signatory to the *Single Convention on Narcotic Drugs 1961* and the subsequent *1972 Protocol Amending the Single Convention* (Single Convention), Australia is required to carefully control and supervise all stages of cannabis cultivation and production and the manufacture of narcotic materials. In the case of narcotic manufacture, these requirements are underpinned by cooperative arrangements with the state and territory governments.

The Department of Health, through ODC, is responsible for issuing licences and permits to manufacture narcotic materials derived from cannabis under the ND Act.

These regulatory functions of the Australian Government and state/territory governments provide a framework for national production and manufacturing quotas to be controlled to ensure that the level of manufacture does not exceed that required to meet domestic medical and scientific needs.

> The export of medicinal cannabis products is prohibited unless registered on the *Australian Register of Therapeutic Goods* (ARTG) and you hold a licence and permit to export under Regulation 10 the Customs (Prohibited Exports) Regulations 1958.

The total quantity of cannabis plants cultivated is based on the quantity of dried cannabis required to fulfil national manufacturing requirements quotas for cannabis derived products. The manufacturing quotas are transmitted to the United Nations International Narcotic Control Board (INCB) for their approval.

To assist in determining the required manufacturing quota of an upcoming year, ODC requires that manufacturers provide detailed information on:

- existing stocks of medicinal cannabis and dried cannabis
- projected sales of medicinal cannabis, including details of customers
- projected manufacture of medicinal cannabis

- quantity of cannabis that will be required to undertake the proposed manufacturing activities.
- projected stocks of medicinal cannabis and dried cannabis at the end of the calendar year.

As a signatory to the Single Convention, the Australian Government recognises the importance of balancing the global demand and supply of narcotic drugs and regulates the industry to ensure that Australian production, manufacture and stocks fall within limits that are consistent with the objectives of the convention.

Manufacture of medicinal cannabis

Manufacture under the ND Act covers a limited scope of what is commonly referred to as manufacturing activities.

On applying for a manufacture licence you will be required to provide details of the activities in your manufacturing process.

Manufacturing activities consists of:

- all forms of extraction from the cannabis plant*
- refining
- concentration
- transformation

Related activities that may be authorised under a ND Act licence include:

- dilution
- mixing of an extract with excipients
- encapsulating or tableting
- supply of the drug
- packaging, transport, storage, possession and control of the drug
- disposal or destruction of the drug

However, if the **related activities** are conducted in isolation from **manufacturing activities** (e.g. you obtained a cannabis extract from a licensed manufacturer) you may not need a licence under the ND Act. If you are unsure whether you require a licence please contact dcs@health.gov.au for advice.

Cannabis Resin*

Cannabis resin is formed by the *separation* of trichomes from the cannabis plant (which involves sieving). This activity is considered PRODUCTION, not manufacture, and requires a licence under Section 8E of the ND Act. Crude vs. purified resin refers to the removal of plant material from the resin.

All other forms of extraction from the cannabis plant, e.g. solvent extraction, is considered MANUFACTURE and requires a licence as described in this guideline.

Supply of medicinal cannabis

Subject to section 11K(2)(b) and (c) of the ND Act, medicinal cannabis may only be supplied:

- for a clinical trial (approved or notified under the *Therapeutic Goods Act 1989)*
- in accordance with an approval under the *Therapeutic Goods Act 1989* (Special Access Scheme Category B)
- by an Authorised Prescriber under the *Therapeutic Goods Act 1989*
- by a pharmacist in a public hospital.

Medicinal cannabis may also be registered on the ARTG.

> Before medicinal cannabis can be supplied to any person, the manufacturer must hold a Good Manufacturing Practice (GMP) Licence.
>
> Extemporaneous compounding is **not permitted** unless you hold a GMP Licence or are a pharmacy within a public hospital.

Medicinal cannabis for research purposes

Subject to section 11K(2)(a) of the ND Act, a manufacture licensee may manufacture medicinal cannabis for research purposes provided the applicant has the appropriate financial resources, other resources and the expertise to carry out the research.

Medicinal cannabis products

The types of medicinal cannabis products that may be manufactured under the ND Act includes extracts and tinctures of cannabis and cannabis resin.

> Cannabis material (e.g. dried cannabis or cannabis resin) may only be supplied to a person licenced to manufacture under the ND Act (Section 10J(2)).

Commonwealth licence to manufacture

A person may apply for a licence to manufacture in accordance with 11G of the ND Act.

The narcotic substances that are subject to the ND Act are defined as '**drugs**' within the ND Act and are those substances that are drugs for the purposes of the Single Convention.

In the case of medicinal cannabis, a **drug** includes:

- cannabis (the flowering or fruiting tops of any plant in the genus *Cannabis* (excluding the leaves when not accompanied by the tops) from which cannabis resin has not been extracted
- cannabis resin (the separated resin, whether crude or purified obtained from any plant in the genus *Cannabis*
- extracts of cannabis and cannabis resin

- tinctures of cannabis and cannabis resin

Terminology

Cannabis and cannabis resin are ***produced*** under the ND Act (Section 8E).

Extracts and tinctures of cannabis are ***manufactured*** under the ND Act (Section 11G).

The powers of the Secretary of the Department of Health to grant a licence or require information to be furnished by an applicant or licensee are delegated to officers (the delegate) within ODC.

Key aspects of the ND Act in relation to granting licences are that the delegate is satisfied that:

- an application for a licence must be made and all required information has been provided
- the applicant (including the body corporate) is fit and proper (including connections and associates of the person) and no serious offence has been committed in the past 10 years
- to grant a licence is consistent with Australia's obligations under the Single Convention
- all reasonable measures have been undertaken to ensure the physical security of the drugs or narcotic preparations in the applicants possession and manufactured under the ND Act licence
- the location of the manufacturing site, facility and proposed security arrangements are acceptable.

In making a decision, the delegate must have regard to:

- all information provided by the applicant, law enforcement agencies, state/territory governments (section 11H (3)(a))
- matters such as conduct of the activities, distribution, use and possession of the drugs and any other matter considered by the delegate as relevant
- the purpose of any proposed research and the financial capacity of the applicant to carry out that research
- the supply of medicinal cannabis only being for a registered product (ARTG), clinical trial, special access scheme, authorised prescriber or by a pharmacist in a public hospital.

The delegate must refuse to grant a licence to manufacture if:

- the delegate is not satisfied that the applicant, body corporate, business associates are fit and proper
- the applicant, body corporate, business associates have engaged in activities which constitute a *serious offence* during the 10 years prior to the date of application
- the delegate is satisfied that the granting of a licence to manufacture is inconsistent with obligations under the Single Convention
- the delegate is not satisfied that all reasonable measures have been (or will be) taken to ensure the psychical security of drugs or narcotic preparations, in the licensee's possession or control and manufactured under the licence

- the delegate is not satisfied of the suitability of the location, facilities, security arrangements
- the provision of further information requested by the delegate has not been complied with
- the delegate is not satisfied that the drug is for the purposes of research in relation to medicinal cannabis products
- the supply of drugs or narcotic preparations is not for:
  - a clinical trial (notified or approved under the approved or notified under the *Therapeutic Goods Act 1989* (the TG Act))
  - supplied in accordance with the TG Act
  - a registered good on the ARTG
  - for supply by a pharmacist in a public hospital

Process aspects – manufacture licence

Applications are processed on a first in, first served basis. However, if your application is incomplete or further information is required, processing of your application will halt and not resume until the required information has been received.

Note that information sought by ODC from other Government Agencies may affect the processing time.

Information required in applications for licences to manufacture

The following is required in order to support an application for a licence to manufacture in accordance with the ND Act.

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

Application type

Application type	Specify whether you intend manufacture for commercial supply or research. Unless the product is registered on the *Australian Register of Therapeutic Goods* (ARTG) manufacture for commercial supply may only be for: · clinical trials · Special Access Scheme under the TG Act · Authorised Prescriber under the TG Act · supply by a pharmacist in a public hospital Export of medicinal cannabis is not permitted.
Licence to manufacture	Specify whether your application is a new application or if you require a new licence following expiration of your current licence.

Application details

Name:	Full Name of the person applying for a licence, including the person acting on behalf of a business or body corporate.
Position held:	Specify the position you hold in the business or body corporate.
Direct phone Number:	Specify a direct phone number you can be contacted on. Do not provide the number of your switchboard.
Mobile number, contact email, out of hours phone number	Ensure you provide your contact details, including after hours.

Business Information

Name of business/company/ organisation	The full name of the business/company/organisation to be the licence holder.
ABN/ACN	Your Australian Business Number or in the case of a body corporate your Australian Company Number.
Site phone number	The contact phone number at the manufacturing site.
Site street address	The street address of the manufacturing site.
Site postal address	The postal address for the manufacturing site or licence holder.

Manufacturing activities

Summary of manufacturing activities	This information will assist us in processing your application.
Extraction of cannabis and/or cannabis resin	The extraction process/es applied to cannabis and/or cannabis resin in order to obtain a concentrate and/or cannabinoids. It does not apply to the production of cannabis resin from cannabis.
Processing, purification of cannabis extracts	Any activity applied to a cannabis extract e.g. refining, concentration, isolation
Supply of manufactured product to another party	Activity related to supplying medicinal cannabis to another manufacturer or formulator, pharmacy, hospital, clinical trial etc.

Packaging of manufactured product into final product	Any activities concerning preparation of medicinal cannabis for distribution into wholesale distribution, clinical trials or to patients.
Export of manufactured product	Only applies to products which are registered on the ARTG. An export only listing on the ARTG does not qualify for medicinal cannabis.
Laboratory analysis of cannabis, cannabis resin, extracts, manufactured products	Includes quality control testing and product testing.
Research	Summarise the research activity.
Other activities	Any other associated activity, which includes packaging, transport, storage, possession and control of the medicinal cannabis.
Drug and products to be manufactured	Specify each product to be manufactured for example Cannabis extract - THC:CBD – 1:10, THC *X*mg/mL: CBD *X* mg/ml Cannabis extract – THC:CBD – THC 0 mg/mL: CBD X mg/mL Schedule 3 must be completed for each drug/product.

Transport

Name	Name of the transport provider used for transporting cannabis material (plant, extracts and final product).
Address	Address of the transport provider.
Service provided	Describe the services being provided for the transport of cannabis material. Note: The Transport provider may need to provide a copy of their State/Territory authorisation.

State/Territory licence

The State or Territory Government may require that you hold additional licences to operate. These may include state/territory licences to manufacture, wholesale, possess and other medicinal cannabis related authorisations. You are not required to have any of these permissions prior to applying for a licence to manufacture under the ND Act; however, you must specify what approvals you will need in this section, or if you already have the approvals, details of the approvals.

Details of licence	Describe what licence(s) or approvals you have (or require) from a State/Territory Government. Use a separate line for each one.
Licence number	The licence or approval number (if you have one) of the state/territory licence or approval.
Expiry date	The expiry date of the state/territory licence or approval.

Fit and proper person requirements

Applicants, business owners, officer holders (e.g. Directors) and associates with a financial interest (including persons with decision making powers or influence, whether financial or not) will be subject to a fit and proper test.

Specify the Full Name, position held, phone number and email address of all relevant persons.

Schedule 1 must be completed by each person listed in this section

Failure to disclose all relevant persons or information required in this application may result in your application being refused (section 11J ND Act).

Senior Person in Charge

The applicant may nominate one (or more) persons to act on their behalf under the licence.

Authorised contacts must be either Directors of the Company, business owners or employees.

Correspondence by the licensee to this office, in relation to their licence, will only be accepted from persons who are confirmed as authorised contacts for the specified licence.

Schedule 2 must be completed by each person in this section.

Note that you do not need to complete Schedule 2 if you have already completed Schedule 1.

Declaration and consent

Ensure that you have read and understood the declaration and consent and that all information in the application form and dossier has been provided.

Schedule 1: Fit and proper requirements

Schedule 1 must be completed in full by the applicant, business owner, company directors, persons with a financial interest and persons with decision making powers or influence.

An certified copy of a national police check certificate must be provided.

The certificate must be no older than three months and must be issued by a Commonwealth or State/Territory Law enforcement agency (a check conducted by an accredited organisation

will not be accepted).

A new national police check certificate will be required every two years.

Schedule 2: Senior Person in Charge

Schedule 2 must be completed by the Senior Person in Charge and deputies (unless you have already completed Schedule 1).

A certified copy of a national police check certificate must be provided.

The certificate must be no older than three months and must be issued by a Commonwealth or state/territory Law enforcement agency (a check conducted by an accredited organisation will not be accepted).

A new national police check certificate will be required every two years.

Manufacturing activities

Complete Schedule 3 for each product specified in part 4 of the application form (Drugs and products to be manufactured).

The information is indicative only and confirmation will be required when you apply for a manufacture permit.

Ensure you specify the calendar year for manufacture.

Dossier Checklist

Part 1: Drugs

Under the ND Act, cannabis, cannabis resin, extracts and tinctures of cannabis/cannabis resin are considered drugs.

For each drug provide:

- specifications (e.g. *CBD:THC 1:1, 15mg/mL CDB, 15mg/ml THC, 10mL vial*)
- end use of drugs (e.g. clinical trials, product formulation)
- estimate quantity of dried cannabis or cannabis resin required to manufacture the drug
- estimate quantity of the drug to be manufactured
- who the drugs will be supplied to.

> For supply to clinical trials, special access scheme or authorised prescriber you will need to provide information of the authority or approval under the *Therapeutic Goods Act 1989.*

Research activities (if applicable)

Provide details of any research related activities you may be conducting. For example:

- extraction efficiency
- stability testing
- formulation studies etc.

For each person involved in the study you must provide details of their qualifications and expertise to conduct the research.

Part 2: Manufacture

Manufacturing process

Describe the manufacturing process in detail, including quality control procedures.

Source of raw materials to be used in manufacture

Provide details of where you will be obtaining the cannabis plant material and/or cannabis resin. If you have a contract or arrangement with the supplier, provide a copy in the dossier.

Part 3: Manufacturing facility

Site map

Provide a site plan showing buildings used for storage, manufacture and administration.

Include the total area and geographical co-ordinates of the land where the facility is located.

Details of facilities

Provide details of whether the facility is owned or leased by you, business (or company) and the name and address of the landlord (if applicable).

Provide details of manufacturing related equipment and storage facilities use to store cannabis plant material and manufactured goods and details of drug vaults/safes, temporary storage areas and loading areas.

Local planning laws/requirements – compliance

Provide documents and evidence that the activities to be undertaken at the manufacturing site comply with local planning laws and requirements.

Security and access details

Risk

Provide a copy of your risk management plant. The management plan should be based on *AS/ANZ ISO 31000:2009 – Risk Management – principles and guidelines.*

Security assessment/audit

Provide a copy of an independent security risk assessment/audit conducted on your facility. If the assessment/audit recommends changes to the facility or procedures provide details what if any changes will be implemented.

Access

Describe all access points and control measures. Provide details of all access controls.

- All external doors and windows must be fitted with secure locks.
- Access should be via an electronic access system with a clear audit trail.
- The manufacturing site must have a lockable intruder resistant perimeter fence and access control gates.
- All areas where cannabis is present must be secured at all times. Access to areas containing cannabis must be restricted and limited to persons who require access as part of their work.
- Records must be kept of all persons entering the facility and areas containing cannabis or drugs.

Surveillance and alarms

Describe the surveillance and alarms systems for your facility and standard operating procedures covering security.

- The perimeter of the site must be visually monitored at all times by a visual recording device suitable for detection of attempted or actual unauthorised access.
- Surveillance (e.g. CCTV) must be on the perimeter, access points and all areas where cannabis material, resins and extracts are located.
- Intrusion detection must be on all areas where cannabis and drugs are located. The system must be monitored at all times.

Disposal and destruction arrangements

Describe the procedures for disposing of the extracted plant matter, excess or waste cannabis material, extracts and other material containing drugs.

- Include a copy of the standard operating procedures for disposal and destruction.

Supply and transport details

Provide a copy of the transport security plan for all applicable activities.

> Drugs being transported by third parties remain the responsibility of the licensee until such time as receipt is confirmed by the end-user.

Transport plans should include details of:

- standard operating procedure for transport of drugs
- safe custody arrangements
- security measures, including escort details and route planning

State/Territory Government licences

Provide copies of any licence or approval issued by a State or Territory Government for the manufacturing site and manufacturing activities.

It is not a prerequisite to hold a state or territory licence relating to manufacture and supply of drugs for this application. However, you must indicate what licences or approvals will be required from your jurisdiction in part 6 of the application form.

You will be required to provide copies of all jurisdictional licences and approvals once issued.

Arrangements with local authorities

Local planning or jurisdictions may have requirements that arrangements are in place with local authorities (police, fire etc.) for matters such as theft/loss, transport, waste disposal etc. Provide details of these arrangements if required.

Standard operating procedures

Provide copies of standard operating procedures (SOP's) concerning security, theft/loss, employment practices, packaging and transport practices.

Part 4: Records

Record keeping arrangements

Provide details of the record keeping system.

Records must be stored in such a way as to be readily accessible and retrievable if required by a person authorised under the ND Act.

Licensees are required to provide monthly manufacturing reports to ODC. A standard reporting template will be provided.

Accurate records must be kept of:

- receipt of raw materials and drugs
- quantities of drugs manufactured and starting materials under your control
- supply and sales of raw materials and drugs
- waste, loss and disposal.

Records must be secure and protected from tampering and unauthorised access.

Procedures must be in place for filing, storage and maintenance of records.

Records collected which related to activities under this licence must not be disposed of without permission of ODC.

Part 5: Staff

Licensees are required to take all reasonable steps not to employ or engage a person to carry out activities authorised by a manufacture licence under the ND Act if the person:

- is aged under 18 years; or
- has been convicted of a serious offence during a period of 5 years before employment or engagement; or

- is undertaking or has undertaken treatment for drug addiction; or
- has a drug addiction; or
- is an undischarged bankrupt; or
- has used illicit drugs in the last five years; or
- been convicted of a drug related offence in the last five years; or
- been convicted of an offence against a law of the Commonwealth, or a State or Territory that involves theft which is punishable by a maximum penalty of imprisonment for not less than three months.

You are required to hold evidence of this information and provide it on request to ODC.

Staff details

Provide the name, address, phone number, description of duties and access areas for employees.

National police certificate

National police certificates must be obtained as a condition of employment and a certified copy provided in the dossier. The certificate should be no older than three months.

Declarations

Ensure Schedule 1 and Schedule 2 for each relevant person (Part 7 and 8 of the application form), including national police certificate is included with the application and signed.

Financial declaration

Provide evidence that you, your business, and/or in the case of a body corporate, the company, has a sound and stable financial background or is not in circumstances that may significantly limit the capacity to comply with obligations under a ND Act manufacture licence.

References

- Single Convention on Narcotic Drugs as amended by the 1972 Protocol
- *Narcotic Drugs Act 1967*
- *Therapeutic Goods Act 1989*
- Customs (Prohibited Exports) Regulations 1958