Australian Government
Department of Health
Office of Drug Control

Medicinal cannabis manufacture licences and permits

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Office of Drug Control

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Introduction

The manufacture of medicinal cannabis products (e.g. extracts, tinctures) requires you to hold a manufacture licence and permit issued under the *Narcotic Drugs Act 1967*, as amended by the *Narcotic Drugs Amendment Act 2016* (the ND Act).

There are two types of licences covering different activities under the ND Act.

1. **Medicinal Cannabis Licence:** (activities related to the cultivation and production of cannabis and cannabis resin)
2. **Manufacture Licence:** (activities such as the extraction of cannabis and/or cannabis resin)

At this time, there are no application fees for a manufacture licence.

You should be aware that all forms of extraction from the cannabis (or hemp) plant for any purpose is an offence under the *Criminal Code Act 1995* unless you hold a manufacture licence and permit under the ND Act.

Extraction processes applied to cannabis seeds for the manufacture of hemp seed oil do not require a licence under the ND Act.

Obligations under the United Nations Convention

As a signatory to the United Nations *Single Convention on Narcotic Drugs 1961*, and the subsequent *1972 Protocol Amending the Single Convention* (the Single Convention), Australia is required to carefully control and supervise the manufacture of narcotic drugs. The Office of Drug Control (ODC), a branch in the Australian Government Department of Health, liaises closely with state and territory governments in relation to the manufacture of narcotic drugs.

The recent amendments to the ND Act, which allow for the cultivation, production and manufacture of medicinal cannabis products, were designed to ensure that Australia can satisfy its international obligations under the Single Convention.

The regulatory functions of the Australian government and state and territory government's provide a framework for establishing national manufacturing quotas to ensure the level of manufacture (and production of cannabis) does not exceed that required to meet domestic medical and scientific needs. ODC establishes the domestic requirements for cannabis (and all narcotic drugs) and furnishes these to the United Nations International Narcotic Control Board (INCB) who determines whether the quantities are acceptable for Australia.

Manufacturing

The definition of manufacture under the ND Act is limited in scope.

A Manufacture Licence under the ND Act is required for:

- all forms of extraction of the cannabis plant (excluding cannabis resin*)
- refining
- concentration
- transformation into other drugs

Activities such as:

- dilution of an extract
- mixing of an extract with excipients
- encapsulating or tableting

generally do not require a licence under the ND Act (i.e. if you obtained the cannabis extract from another party for the purposes of reformulation, packaging). However, these activities are subject to the *Therapeutic Goods Act 1989* (e.g. GMP Licence) and applicable state or territory legislation.

*cannabis resin refers to the separated resin from the cannabis plant and is considered 'production'. Production of cannabis resin requires a *Medicinal Cannabis Licence* under the ND Act.

Multiple regulators

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ODC regulates medicinal cannabis manufacture to ensure:

- manufactured quantities are consistent with domestic requirements
- diversion risk is reduced through cross jurisdictional cooperation and liaison
- compliance with Australia's international reporting obligations to the United Nations under the Single Convention

Therapeutic Goods Administration

As a medicine, medicinal cannabis products are regulated by the Therapeutic Goods Administration (TGA), who regulate:

- access to therapeutic goods
- quality of therapeutic goods.
- Good Manufacturing Practice (GMP)

Both ODC and TGA are part of the Australian Government Department of Health. Together they make up the Health Products Regulation Group.

Generally, if you hold licence to manufacture medicinal cannabis products under the ND Act, you may also need to hold a GMP Licence from TGA.

State/Territory Governments

The State and Territory Governments may have their own legislation and licensing requirements to cover manufacture, wholesale, supply and patient access to medicinal cannabis products.

Under state/territory legislation medicinal cannabis products manufactured under the ND Act are Schedule 8 Controlled Drugs as scheduled in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

A manufacturing licence issued under the ND Act does not excuse you from having to obtain the required licences/authorisations from the State or Territory Government, nor does it excuse you from complying with state or territory law.

ODC licences and permits

You are required to hold both a manufacture licence and manufacture permit under the ND Act in order to manufacture medicinal cannabis products.

The purpose of the licence is to authorise specific 'manufacturing' activities that may be conducted and place conditions and obligations on the licensee (in addition to those specified in the ND Act and regulations).

The permit places limits on product types and quantities that may be manufactured by the licensee.

Licences

Subject to conditions, a manufacture licence issued under the ND Act allows the licensee to manufacture specified drugs and products and activities related to manufacture. However, unlike a *medicinal cannabis licence*, a manufacture licence does not authorise any activity to the exclusion of state or territory law.

Licences may be granted for a specific period of time and apply to a specific manufacturing site.

Manufacturing activities cannot commence until you have been granted a permit to manufacture under the ND Act.

A licence may also be conditioned to satisfy certain requirements such as a GMP Licence from the TGA and/or the appropriate State or Territory Licence.

Permits

Manufacturing activities may only commence if granted a permit to manufacture (subject to any State or Territory requirements)

A manufacturing permit will:

- characterise the drug (i.e. cannabinoid content, concentration)
- set a maximum quantity of the drug manufactured
- set a maximum quantity of the drug that may be held at any given time at the manufacturing site
- specify the period in which manufacturing may occur

Number of licences and permits

There is no limit to the number of manufacturing licences that can exist.

Manufacture licences are site specific and generally only one licence will be issued per site. A licensee may hold more than one licence if they have multiple manufacturing sites.

A licensee may be issued multiple permits per site (e.g. for different drug types).

Similarly, there is no limit to the number of permits that can exist.

Preconditions

There are preconditions that apply to making an application for a licence. We will not accept your application if your application does not meet the preconditions.

Licence preconditions

It is a precondition of applying for a licence that you are able to demonstrate that the drug and/or product to be manufactured for at least one of the following:

- for the purposes of research in relation to medicinal cannabis products
- for the purpose of a clinical trial (in accordance the *Therapeutic Goods Act 1989*)
- for supply as an unregistered medicine in accordance with the *Therapeutic Goods Act 1989* (e.g. special access scheme, authorised prescriber)
- for supply as a registered good within the meaning of the *Therapeutic Goods Act 1989*.

It is a further precondition that your licence application must be effective before it can be accepted for assessment. An application will be considered to be effective when:

- all fields of the application form are filled in
- all required documents are present.

If you provide an application that does not meet the preconditions above, we will advise you and offer you the opportunity to rectify. Your application will not be further considered until these preconditions are satisfied.

Note that an application received with incomplete documents, or inaccurate information within application fields, may still be considered effective, but will then require further information exchanges in the assessment process. All applicants should note that Sections 137.1 and 137.2 of the *Criminal Code Act 1995* create offences for providing false or misleading information or documents to a Commonwealth entity, which includes the Department and all parts of the Department.

Once an application is considered effective, the formal assessment process begins. This formal assessment process will consider the sufficiency of the responses to the information requirements.

Permit preconditions

It is a precondition of applying for a permit that you are able to demonstrate that manufacture will be in accordance with any applicable State or Territory law and you have either provided evidence that:

- supply will be as an unregistered good in accordance with the *Therapeutic Goods Act 1989* (e.g. special access scheme, authorised prescriber) or clinical trial, or
- you have provided evidence that manufacture is solely for the purpose of research related to medicinal cannabis products, or
- the product is registered on the Australian Register of Therapeutic Goods (ARTG)

Licence requirements

There are an extensive set of requirements that must be met to be granted a licence. These include your suitability as the applicant to hold a licence and the suitability of your associates (business, familial, or otherwise) to be associated with a medicinal cannabis business, as well as the security design and location of any proposed manufacture site.

We require extensive information around these and other issues in support of a licence application. The purpose of such requirements are to allow us to make comprehensive assessments of the suitability of licence applicants and their associates, as well as adequacy of security and other processes around the manufacture of medicinal cannabis.

Fit and proper persons requirements

Please carefully read and consider the implications of Part 2 of the ND Act (fit and proper person requirement) and the associated regulations. Being able to satisfy the fit and proper person test for both you and your relevant business associates is a critical step in successfully obtaining a licence.

The fit and proper person test is quite strict and will seek a substantial amount of information about you and your associates. The purpose of this rigour is to ensure that you are an individual of good repute who can be entrusted with the possession of cannabis and the manufacture of products from cannabis to eliminate the potential for diversion.

Note that the consideration of your fitness to hold a licence is against a range of criteria. Failure to satisfy a single criterion may not necessarily be grounds for exclusion from holding a licence (with the exception below under criminal background).

Criminal background

You will be asked for details of your history of criminal convictions. This includes all convictions, spent or otherwise.

You will also be asked whether you have engaged in conduct that would constitute a serious offence in the last 10 years. These are defined in the ND Act and include drug offences and offences involving dishonesty or fraud with a maximum penalty of not less than 3 months; or any other offence with a maximum penalty of not less than 5 years.

Please note that this is a **mandatory exclusion** criterion. If you have engaged in conduct that would constitute a serious offence in the last 10 years, you are ineligible to hold a licence unless you can satisfy the decision maker that you are eligible for an exemption for special or extraordinary circumstances.

Exemptions for special or extraordinary circumstances

The Narcotic Drugs Act contains specific clauses designed to allow persons who may have previously been involved in the use or supply of cannabis for compassionate or medicinal purposes only to participate in the medicinal cannabis scheme. These exemptions allow an applicant to participate in the scheme even where that applicant may otherwise fail the test around conduct that would constitute a serious offence. The exemptions deal with activity constituting an offence related to cannabis cultivation or supply.

When filling in the application form, you will be prompted to indicate whether you wish to make a declaration that might attract this exemption. If you respond in the positive, we will separately approach you under Section 14J(1) of the ND Act inviting you to make such disclosures. The

purpose of this separate approach is to ensure that any such disclosures attract the privilege against self-incrimination arising from giving such information under Section 24B of the ND Act.

Please note that this protection against self-incrimination only applies to action the Department of Health might take in relation to information or evidence provided in relation to an offence. This protection does not extend to evidence or information separately collected by law enforcement entities in the course of their activities.

Civil penalties or previous regulatory non-compliance

You are required to disclose any civil penalties regardless of type imposed on you within an Australian jurisdiction.

You are also required to disclose any regulatory non-compliance (such as breaches of licence) that has attracted a revocation or suspension of a licence or permit and that relates to the prohibition or regulation of drugs.

Your business associates, connections and family

You will be asked for details of your business associates, your immediate family and any connections that we should be informed of, or which if they come to light at a later point, that might give rise to a potential revocation or suspension of your licence.

Specifically, your:

- business associates are those who have the ability to influence the conduct of your enterprise, either due to having a financial interest or through other means
- immediate family includes parents, siblings, partner and children (those above 18 only)
- connections are those persons who have the ability to influence your business decisions

Please be aware that your relevant business associates will also come under substantial scrutiny and must satisfy the fit and proper person test independently. It is the licence applicant's responsibility to facilitate such processes and failure to do so may affect your ability to obtain and retain a licence.

Business experience and financial stability

You will also be asked to demonstrate your ability to conduct a stable business. The purpose of this is to prevent financial instability leading to the risk of diversion into the black market.

This requirement will look at your finances and funding arrangements, as well as your previous business experience.

Security requirements

It is important to remember that one of the key principles of the ND Act is the prevention of diversion of cannabis for illicit use. Consequently, the security requirements for a licence applicant are robust and will require your careful attention.

Security is made up of a number of key components:

- physical (site) security of the manufacture facility and equipment
- information security including records management
- personnel security of staff and contractors

In addition, security must be considered as an end-to-end process and therefore must cover storage, handling, transport and engagement in third party controlled processes (such as analytical testing of extracts and/or products).

The successful licence applicant (the licence holder) is responsible for all elements of security for activities conducted under licence or under permit. In the event of a security breach, regardless of how it occurred, the licence holder is responsible for satisfying the Department of Health that security principles and practices in place are sufficient to allow the continuation of licence related activities.

It is important to remember that security is only as good as the weakest link in your systems, so it may be valuable for you to consider the effectiveness of your security solutions holistically.

Guidelines will be made available on the following processes.

Physical (site) security, equipment and manufacturing process

Physical site security deals with access to the premises/location, as well as controls around movement within the location and access to cannabis and the extracted cannabis material.

Manufacturing processes will cover the extraction of cannabis, disposal of waste material and other refining processes conducted on the material including chemical analysis.

Physical security will consider elements such as intruder resistant design, access controls between areas within the location, access to cannabis by staff or contractors, monitoring and recording of such access, disposal of extracted material, storage of extracts, alarms and guarding solutions and other elements of physical security designed to prevent diversion.

Information security including records management

Information security is important to ensure that your detailed security arrangements are not accessed by third parties.

Consequently, your information and records should be kept under close control. Note also that part of the ODC inspection function will include the perusal of records relating to activity conducted under licence, which must be complete and detailed.

Personnel security for staff and contractors

A weakness of any security system is that it must take into account the actions of staff, contractors, visitors and other people who will have access to the site. While physical security can handle elements such as visitor logs and access controls for temporary access instances, a more rigorous personnel security model is necessary to support broader security measures.

It will be a condition of your licence that you take reasonable steps to ensure that your employees and contractors are suitable persons.

You must have in place mechanisms to ensure that your employees and contractors can meet the expectations outlined under Section 12H of the ND Act and the associated regulations.

At a minimum this is likely to require review of the prospective employee's criminal history, including obtaining a National Police Check, and employment history. It is also likely to require that you to ask questions of prospective employees around drug use and dependencies.

Storage, handling, transport and engagement for third party processes

Security in the storage of cannabis (and extracts), its transport and,when necessary, in engaging third parties to assist in processing or destruction, are significant potential weak points in an overall security model.

For storage, it is likely that the cannabis plant material prior to extraction may attract a greater diversion risk than other elements of a facility. Additional controls around access may therefore be appropriate.

For handling, the licence holder may see value in using specific controls around the internal handling of cannabis to prevent employee diversion.

Transport and engagement with third party processes require your specific attention as the controls around site security are no longer effective. It is your responsibility to demonstrate how security might be met in such processes. This may include reliance on other sub-contracted entities to assist in transport, or on the security arrangements in place at other facilities where third party activity may occur.

Other considerations

In addition to the licence requirements discussed above, there are a range of other issues you may wish to take into consideration.

- Undertakings you make in relation to your security arrangements will (if accepted) be transferred into conditions on your licence. In other words, if you describe a set of security parameters in your application, we will hold you to those.
- There will be an expectation that you will transfer your security planning into operational procedures and demonstrate how this will take effect.
- You will find that there are relevant state, territory and other Commonwealth laws that have effect within a medicinal cannabis enterprise. It is your responsibility to consider these and, if necessary, seek advice on your business model from the relevant agency. Some examples might include (but are not limited to):
  - workplace safety and workers compensation
  - local planning permits
  - licencing around heavy machinery
  - required qualifications or training for key staff
- In describing your capacity to undertake the enterprise, it may be relevant for you to submit your business plan and we will ask you to have formally undertaken an assessment of critical risks. For manufacture licences relating to medicinal cannabis research, your business plan should include your research outline and any associated approvals from the relevant sponsoring entity (if applicable).
- It is likely that as you develop your site, pragmatic issues may arise that will require you to seek to vary the conditions of your licence. It is important that you communicate these clearly and swiftly with us to support dialogue for resolution. In doing so, note that any proposed modifications must at least meet (if not exceed) the risk mitigations outlined in your risk assessment.

How to apply for a licence

To apply for a licence, please fill out the application form, attach the relevant documents and submit to ODC. Make sure you have read the guidelines to your applications.

You may apply for more than one type of licence at the same time. However, you need to have been granted a licence before you can apply for a permit.

Prior to applying for a licence there are preconditions that you must satisfy and a variety of documents that must be prepared to accompany your submission.

Processing time

There is no statutory processing time for licence application assessment; however, we aim to assess applications within 20 working days. Note that the time frame does not include the time it takes for law enforcement or other state and territory licencing agencies or regulatory authorities to respond to requests for information; nor does it cover the time you might take in responding with further information or documents.

ODC will provide you an update on progress on your request, but will only do so in relation to ODC activity. We will not comment on processes underway in other entities, nor will we provide you feedback on information provided from law enforcement or other state or territory authorities.

Fees and refunds

There are no fees at this time for a manufacture licence or manufacture permit.

Lodgement process

ODC prefers electronic lodgement through secure web-based application forms.

Where it is not possible to submit electronically, then please print out the application form and submit physically.

When submitting physically, there are likely to be quite a number of attached documents. If possible, ODC would prefer those to accompany your application form in a digital media format (on a CD or USB).

The address for manual lodgement is:

Drug Control Section
Office of Drug Control
Department of Health
Post Office Box 100
Woden, ACT

Should you require assistance on the lodgement processes, please direct enquiries to dcs@health.gov.au.

Application assessment and communication

Once we have received your application, we will check that you have met the preconditions. If your application does not meet the preconditions, we will advise you of this and offer you the opportunity to rectify. Your application will not be further considered until these preconditions are satisfied.

This will initiate the assessment of your application. We will assign each application a case officer who is responsible for the initial assessment process, including communicating with you and seeking additional information where necessary. Note that to support consistent decision making and avoid improper dealings, your case officer will not be the person making the eventual decision on the grant or otherwise of a licence.

Information and documents

The information requirements for a licence application can be complex and broad. It is quite likely that in assessing your application, you will be required to provide further information or clarification of material provided. Your responses to such requests will facilitate the pace of application assessment.

ODC will also ask for additional information from state and territory law enforcement agencies (including, and beyond that contained within, normal criminal history checks) and from other state and territory licencing agencies or regulatory authorities.

These information checks are to support that the applicant and their relevant business associates meet the stringent fit and proper persons test under the ND Act and other provisions.

In requesting such information, either from you, or from other parties, it is likely that such processes will require additional time to complete.

Limits on requests for further information

While we will work with applicants to facilitate appropriate licence applications, the onus remains on you as the applicant to assist us in this process.

If you request further time, we may accommodate that request, or otherwise, at our reasonable discretion.

How to apply for a permit

A manufacture permit specifies the amount of drugs that can be manufactured, the amount of drugs that can be held in stock at any one time, the period when manufacturing may occur and the period the permit is in force.

The purpose of using a permit system in tandem with licencing is to control quantities of manufactured drugs and ensure these quantities do not exceed those required for the market conditions. Such control over quantities is critical in ensuring that Australia can continue to meet international obligations around narcotic drugs.

To apply for a permit, please fill out the application form, enter your licence number, attach the relevant documents and submit to ODC.

Prior to applying for a permit there are preconditions that you must satisfy and a variety of documents that must be prepared to accompany your submission.

Processing time

There is no statutory processing time for permit application assessment, but we aim to assess applications within 20 working days.

Fees

At this time there is now fee for a manufacturing permit.

Application assessment and communication

Once we have received your application, we will check that you have met the preconditions, then assign a case officer who has responsibility for the initial assessment process, including communicating with you and seeking additional information where necessary.

Information and documents

The information requirements for a permit are not as extensive as those for a licence, because having successfully obtained a licence, you have already provided the information needed and been assessed against the licence criteria.

You will be asked to outline the following characteristics of any proposed manufacture under your permit:

- characterise the drug (i.e. cannabinoid content, concentration)
- set a maximum quantity of the drug manufactured
- set a maximum quantity of the drug which may be held at any given time at the manufacturing site
- specify the period in which manufacturing may occur
- details of next party in the supply chain

Note that while the information requirements for permits are less than those for a licence, we may still need to ask additional questions.

Limits on requests for further information

While ODC will work with applicants to facilitate appropriate permit applications, the onus remains on you as the applicant to assist us in this process.

If you request further time, we may accommodate that request, or otherwise, at our reasonable discretion.