



Australian Government
Department of Health
Office of Drug Control

Commonwealth Medicinal Cannabis Initiative

Information Sessions

4-6 October 2016

Reminder

- Please turn phones off or put on silent
- No voice or video recording
- Please keep questions for the Q&A session at the end
- Housekeeping

Agenda

What will be discussed?

- Progress of the scheme so far
- Legislation and international conventions
- 'Fit and proper person' requirements
- Document and information requirements for applications
- Security requirements
- Fees
- Revocation and suspension

Progress of the scheme

What has been achieved so far?

- Extensive consultations with states and territories
- Document and information requirements for applicants have been determined
- Security requirements have been finalised
- Fees have been confirmed however charges are yet to be finalised
- Application forms are in the final stages of development
- ODC will start accepting applications from October 30

Introduction to the Regulatory Framework

What needs to happen before October 30

- Regulations to be finalised after approval by the Minister and Executive Council
- Guidelines for industry to be finalised
- Application forms and other documents to be published to the ODC website

Domestic Legislation

Narcotic Drugs Act 1967

The Act was amended in February 2016 to permit the Commonwealth to allow for cannabis cultivation for medicinal and related scientific purposes in accordance with the *Single Convention on Narcotic Drugs, 1961*

Further amendments to the Act are currently before Parliament and deal largely with the use of sensitive law enforcement information.

International conventions

Single Convention

The United Nations *Single Convention on Narcotic Drugs 1961* aims to combat drug abuse through coordinated international action.

The Convention seeks to limit the possession, use, trade, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes. It also combats drug trafficking through international cooperation to deter and discourage drug traffickers.

Fit and proper persons

You must be a 'fit and proper person' to successfully apply for a licence.

- Part of the assessment of your licence application
- Applies to your business associates
- Extends to looking at your non-business related connections and your relatives.

Fit and proper persons cont.

What does ODC take into account?

- Convictions
- Imposition of civil penalties
- Regulatory breaches related to drugs
- Financial situation of individuals
- Connections, associations and family

A person may fail to satisfy an element of the requirement and still be considered 'overall' to be a fit and proper person to hold a licence.

Fit and proper persons test cont.

Suitable staff

Licence holders must take *all reasonable steps* to ensure that staff members employed or engaged do not present a risk of diversion of cannabis.

There are a number of criteria that determine a prospective staff member to be **unsuitable** such as current or previous drug addiction, criminal convictions, bankruptcy and more.

Specific details relating to these criteria will be made available on the ODC website.

Information requirements – licence applications

Medicinal cannabis licence applications (cultivation)

- Identity and contact details
- Activities the applicant proposes to undertake
- Location details including ownership or leasehold and access to the location

Information requirements – licence applications

Medicinal cannabis licence applications (cultivation)

- Details of arrangements in place to ensure security
- Details of arrangements with emergency services and local government authorities to deal with the loss, theft, spoilage, disposal or destruction of cannabis (see security guidelines).

Information requirements – licence applications

Medicinal cannabis licence applications (cultivation)

- Whether the applicant has applied, or proposes to apply for any other licence under the Act.
- Information about whether the applicant is a fit and proper person including.

Information requirements – licence applications

Cannabis research licence applications

In addition to the information requirements of the medicinal cannabis cultivation licence application:

- How the research relates to medicinal cannabis or medicinal cannabis products
- Details of financial resources, other resources and expertise
- If applicable, details of approval from a research committee or research grant issued

Information requirements – licence applications

Manufacturing licence applications

In addition to the information requirements of the medicinal cannabis cultivation licence application:

- Details of drugs proposed to be manufactured
- Details of proposed end use of drugs
- Record keeping arrangements including the quantities and amount of starting material
- Information regarding products manufactured for research, clinical trials or supply to the public.

Document requirements – licence applications

Medicinal cannabis licence applications (cultivation)

- Identification documents
- Evidence of financial stability
- A site plan
- A detailed floor plan
- A copy of standard operating procedures and policies that will be used
- A risk management plan

Equivalent documentation is required for cannabis research licence applications and manufacturing licence applications.

Information requirements – permit applications

Medicinal cannabis permit applications (cultivation)

- Types and strains of cannabis
- Range of THC and CBD in cannabis and any other cannabinoids
- The maximum size of the cannabis crop during the period of the permit
- The maximum number of cannabis plants
- The period during which the plants will be cultivated
- Details of the source of the plants

Equivalent information requirements for cannabis research permit applications.

Information requirements – permit applications

Production

- Maximum quantity of cannabis or cannabis resin to be produced
- Maximum quantity of cannabis necessary for the applicant to have in their possession or control at any time
- The period in which the cannabis or cannabis resin will be produced.

Information requirements – permit applications

Manufacture applications

- The details of
 - drugs proposed to be manufactured
 - proposed end use of the manufactured drugs
 - starting materials
 - maximum number of drugs that are proposed for manufacture
 - maximum number of drugs necessary to have in possession or control at any time
 - period during which the drugs will be manufactured
 - how the applicant will comply with sections of the Act regulating the end use of the drugs

Document requirements – permit applications

Cultivation and production

- Copies of all relevant *contracts* in place between the applicant and the holder of a licence under the Act to authorise:
 - The supply of cannabis
 - The production of cannabis
 - The manufacture of one or more medicinal cannabis products
 - The manufacture of a drug for the purposes of research
- If the applicant proposes to cultivate cannabis plants in accordance with the permit, *evidence* of:
 - The types and strains of cannabis proposed to be cultivated; and
 - The range of concentration of THC and CBD likely to be contained in the cannabis plants proposed to be cultivated.

Document requirements – permit applications

Research

The following documentation may be required in addition to a medicinal cannabis cultivation permit application:

- Copies of all relevant contracts in place between the applicant and the holder of a licence under the Act to authorise the production of cannabis

Manufacture

There are no documentation requirements for permit applications.

Security requirements

There are a number of underpinning security principles that should be reflected in your security arrangements:

- Deter – discouraging security breaches
- Delay – slowing down attempts to remove cannabis
- Deny – prevention of unauthorised access
- Detect – detecting and responding to unauthorised access
- Defend – how you respond to a breach

Security requirements cont.

Risk of diversion

Diversion of cannabis to illicit use is the most significant risk facing the medicinal cannabis scheme. Theft and loss are the two most likely ways in which diversion can occur.

- *Unauthorised access by an external person*
- *Unauthorised access by an employee or visitor*
- *Authorised access by an employee or visitor*

The licence holder is required to notify both their local law enforcement agency and ODC of the event as soon as possible.

Security requirements cont.

Key concepts for security arrangements

- *Access Controls*
- *Intruder resistance*
- *Crop integrity*
- *Detection and response*
- *Procedural security measures*
- *Disposal and destruction of cannabis*

Security requirements cont.

- A licence holder must demonstrate effective controls before activities can commence
- Failure to comply could result in revocation of the licence or referral to law enforcement
- Any changes arrangements must be reported to ODC for assessment
- Where two entities operate on a single site under separate licences, the cultivation licence holder is responsible for the physical site security.
 - The production licence holder will have additional responsibilities around handling, transport and storage.

Security requirements cont.

Transportation of cannabis

The key principle of transport security is to develop arrangements that adapt according to the risk associated with the movement.

The licence holder remains responsible for the cannabis when transport is outsourced.

Fees

Cost recovery

ODC charges for the conduct of regulatory activity, including assessing your application, processing of variations, and for the conduct of inspections.

Fees are non-refundable!

Commonwealth Policy: '*Entities should generally set charges to recover the full cost of providing regulatory activities*'.

Fees cont.

Cost recovery

The medicinal cannabis program has the following key outputs for which cost recovery is required:

- Medicinal cannabis licence
- Medicinal cannabis permit
- Variation to licences
- Variations to permits
- Compliance activities, including routine and non-routine inspections with plant sampling and site mediation.

Fees cont.

| Application | Fee |
|---|---------|
| Application for a medicinal cannabis licence | \$5,290 |
| Application for a medicinal cannabis permit | \$1,830 |
| Application for a cannabis research licence | \$5,290 |
| Application for a cannabis research permit | \$1,830 |
| Application for a variation of a medicinal cannabis licence | \$4,150 |
| Application for a variation of a medicinal cannabis permit | \$1,730 |
| Application for a variation of a cannabis research licence | \$4,150 |
| Application for a variation of a cannabis research permit | \$1,730 |

Revocations and suspensions

Why a licence or permit would be revoked

- If a licence holder is no longer considered to be a fit and proper person
- If a business associate of the licence holder is no longer considered to be a fit and proper person.
- If the licence holder (including any officer or director within a body corporate) has engaged in conduct that constitutes a serious offence since the licence was granted.

A number of other circumstances exist in which the Secretary has discretion and **may** revoke a cannabis licence.

Revocations and suspensions cont.

Understanding suspensions

The Secretary may suspend a licence if satisfied that a reasonable ground exists.

Licence holder can still tend to, nurture or store cannabis plants under the licence holder's possession or control.

Undertaking production under a suspension is an offence unless the Secretary has permitted such activities.

Revocations and suspensions cont.

Directions

Prior to the stages of revocation or suspension however, ODC may issue a set of directions to a licence holder in an attempt to rectify situations which might lead to such regulatory activity.

Whether revocation, suspension or directions, ODC will work with the licence holder to arrive at appropriate and lawful outcomes.

Contact us

Cultivation: mcs@health.gov.au

Manufacture: dcs@health.gov.au



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Questions
