



# Commonwealth Fact Sheet



# **MEDICINAL CANNABIS**

If your project involves the cultivation, production or manufacture of cannabis for medicinal and related research purposes you must obtain a medicinal cannabis licence.

#### 1. What approvals do I need?

The cultivation, production and manufacture of medicinal cannabis in Australia is subject to stringent control under the *Narcotics Drugs Act* 1967 (Cth) (Narcotic Drugs Act).

There are three types of licences under the Narcotic Drugs Act that relate to medicinal cannabis:

- medicinal cannabis licence authorising cultivation or production or both
- cannabis research licence authorising similar process for research purposes
- manufacturing licence authorising the manufacture of a drug or product.

Factors that are considered in deciding whether a licence should be granted include whether: the applicant is a fit and proper person to hold a licence, its business associates are fit and proper to be associated with the holder of a licence, and the suitability of the proposed location, facilities and security, amongst other things. Before any activity under a licence can commence, the licensee will need to apply for and be granted a permit, which will set out the types and amount of cannabis that can be grown and/or produced or manufactured and the types and quantities of medicinal cannabis products that can be manufactured under the licence.

### 2. Who provides approvals?

The Office of Drug Control (ODC) provides the three types of licences that relate to the cultivation, production

and manufacture of medicinal cannabis. Information on applications and guidance is located on the ODC website here.

The <u>Therapeutic Goods Administration</u> (TGA) is responsible for ensuring that the therapeutic goods available for supply in Australia are safe and fit for their intended purpose. The TGA administers the <u>Therapeutic Goods Act 1989</u> (Cth) (the Act), which establishes the regulatory framework for all medicines in Australia. Information and guidance materials located on the TGA here.

State/Territory governments may also require approvals.

# 3. How do I get Australian Government approval?

Application forms and guidance material are provided on the ODC website <a href="here">here</a>.

## 4. More information

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For more information on the cultivation of cannabis for medicinal and related research purposes please go to the Office of Drug Control.

## **Major Projects Facilitation Agency**

If you would like assistance to identify the regulatory obligations for your project, please visit our <u>Online Tool</u> or contact us:

Email: mpfa@industry.gov.au

This fact sheet provides general information and does not constitute legal advice. You should seek independent legal advice tailored to your individual circumstances. The Major Projects Facilitation Agency (MPFA) assists Major Project Proponents to navigate the approvals process. The MPFA does not grant approvals, nor administer this Act or Regulations.

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