Australian Government
Department of Health
Therapeutic Goods Administration

Medicinal cannabis products: overview of regulation

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This information about medicinal cannabis is for patients, health professionals, cultivators, manufacturers and researchers.

The Australian Government is working towards facilitating access to medicinal cannabis products for patients with a medical condition for which there is evidence to support its use.

Access to medicinal cannabis is regulated at Commonwealth and State/Territory levels.

Facilitating access to medicinal cannabis

Medicinal cannabis became a controlled drug in the Poisons Standard (//www.tga.gov.au/publication/poisons-standard-susmp) on 1 November 2016. As a result of this change, medicinal cannabis can be prescribed under the provisions of a controlled drug (Schedule 8) of the Poisons Standard. However, whether medicinal cannabis can be prescribed in a particular jurisdiction depends on whether the state or territory has adopted the change.

Check the website of your state or territory health department to find out whether medicinal cannabis products are allowed in your state or territory.

- ACT Health (http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services)
- NSW Government Health (http://www.health.nsw.gov.au/pharmaceutical/Pages/cannabis-products.aspx)
- Northern Territory Department of Health (http://www.health.nt.gov.au/)
- Queensland Health (https://www.health.qld.gov.au/)
- SA Health (http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content

/sa+health+internet/about+us/department+of+health
/public+health+and+clinical+systems
/medicines+and+technology+policy+and+programs)

- Tasmanian Department of Health and Human services (http://www.dhhs.tas.gov.au/psbtas)
- health.vic (https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis)
- Government of Western Australia Department of Health (http://ww2.health.wa.gov.au/)

Multiple laws and regulators

The state and territory governments and the Australian Government Department of Health all play a part in regulating medicinal cannabis in Australia.

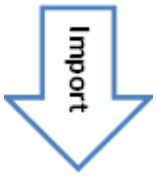
State and territory health departments have a role through medicine scheduling and particular requirements on how controlled drugs, including medicinal cannabis, may be authorised for use by specified patient groups in their jurisdiction.

The Australian Government Department of Health regulates medicinal cannabis products through:

- the Office of Drug Control (ODC) (https://www.odc.gov.au), which regulates controlled substances to prevent diversion and illicit use. ODC administers the *Narcotic Drugs Act 1967 (https://www.legislation.gov.au/Search/narcotic drugs act)* so that Australia can satisfy its international obligations under the United Nations *Single Convention on Narcotic Drugs 1961 (https://www.unodc.org/unodc/en/treaties/single-convention.html)*. ODC grants licences and permits:
  - for cultivation and production
  - for manufacture (in order to prevent diversion)
  - to import.
- the Therapeutic Goods Administration (TGA), which regulates medicines by administering the *Therapeutic Goods Act 1989 (https://www.legislation.gov.au/Series/C2004A03952)* to:
  - ensure the way manufacture is conducted (//www.tga.gov.au/good-manufacturing-practice-overview) (to produce medicinal cannabis products such as oils or tinctures) results in high quality medicines
  - assess the quality, safety and efficacy of medicines before entry on the Australian Register of Therapeutic Goods (ARTG) (//www.tga.gov.au/australian-register-therapeutic-goods), which allows use in Australia
  - provide, in appropriate circumstances, access to medicines that have not been approved for use. This is anticipated to be the major route for patient access to medicinal cannabis products over the next few years.

How the legislative requirements work together

The following table provides an overview of how the legislative requirements work together.

Process step		Therapeutic Goods Act (TGA)	Narcotic Drugs Act (ODC)	States and territories involved?
Patient need Medical authorisation		Special access scheme (//www.tga.gov.au/form/special-access-scheme) OR Authorised prescriber (//www.tga.gov.au/form/authorised-prescribers)	No	Yes
Import (if obtaining from overseas)		Responsibility of the sponsor	Licence (https://www.odc.gov.au/licences) and permit (https://www.odc.gov.au/import-applications-permits) to import controlled substances	Yes
Distribution	**PATIENT** with medical authorsation	No	Responsibility of the licensee	Yes

Process step	Therapeutic Goods Act (TGA)	Narcotic Drugs Act (ODC)	States and territories involved?
Manufacture of medicine in its dosage form	Licensable	Licences and permits	Yes
Manufacture of active ingredient	Licensable	Licences and permits (https://www.odc.gov.au/manufacturers-1)	Yes
Harvest (termed 'production' in the Narcotic Drugs Act)	No	Licences and permits	No
Cultivation	No	Licences and permits (https://www.odc.gov.au/cultivators)	No

1. These access arrangements apply unless an appropriate medicinal cannabis product is on the ARTG and available.
2. Access requirements still apply.

Access

Medicinal cannabis is a controlled substance that is regulated to prevent diversion and illicit use. For this reason, demand and supply are linked in the regulatory process. For permits to be issued to Australian manufacturers, there needs to be communication between health professionals obtaining access for patients and medicinal cannabis manufacturers.

Patient need

Patients will only be able to access medicinal cannabis if they:

- live in a state or territory where it is not a prohibited substance
- obtain a prescription from an appropriate medical practitioner, who obtains permission from:
  - the state or territory

- the TGA

for you to obtain a specific medicinal cannabis product.

Medical authorisation

Access to medicinal cannabis is available through:

- the authorised prescriber scheme (//www.tga.gov.au/form/authorised-prescribers)
- Special access scheme (//www.tga.gov.au/form/special-access-scheme) category B.

If you wish to prescribe medicinal cannabis to a patient, you will need to apply to the TGA through one of these schemes.

Make sure that medicinal cannabis is not a prohibited substance in your state or territory.

For more information see Access to medicinal cannabis (//www.tga.gov.au/access-medicinal-cannabis-products).

Quality

Medicinal cannabis products must conform with Therapeutic Goods Order 93 (Standard for Medicinal Cannabis) (//www.tga.gov.au/therapeutic-goods-orders) (TGO 93).

- TGO 93 applies to: approved and unapproved products
- imported and Australian manufactured products
- products supplied in Australia or exported from Australia.

For details on exactly what TGO 93 applies to, see *Conforming with TGO 93 (Standard for Medicinal Cannabis)*.

We require a declaration of conformity with TGO 93 for unapproved medicinal cannabis products. This declaration is to be made by the manufacturer with responsibility for quality control testing of the finished product. This is because TGO 93 is highly technical and the person importing and supplying the product in Australia may be a medical practitioner, not a commercial sponsor.

For more information about declaring conformity with TGO 93, see Access to medicinal cannabis products (//www.tga.gov.au/access-medicinal-cannabis-products).

Import

Importers require:

- an importation licence (https://www.odc.gov.au/licences) from ODC
- an importation permit (https://www.odc.gov.au/import-applications-permits) from ODC.

Local cultivation and supply

Cultivation and harvest (production)

If you want to become involved in the cultivation and production (harvest) of medicinal cannabis, you are required to hold a cultivation and production licence and permit(s) (https://www.odc.gov.au/cultivators) under the Narcotic Drugs Act. It is also possible to hold separate cultivation and production licences under the Narcotic Drugs Act. You are not required to hold any licences under the Therapeutic Goods Act if you are carrying out only these steps.

Manufacture

If you are (or want to be) a medicine manufacturer in Australia and you want to become involved in the manufacture of medicinal cannabis, you are required to comply with each of the applicable legislative frameworks:

- any relevant state or territory licences or approvals
- ODC manufacture licence (https://www.odc.gov.au/manufacturers-1) under the Narcotic Drugs Act in combination with the associated permit(s)
- Good Manufacturing Practice (GMP), regulated by the TGA. See GMP compliance for the manufacture of medicinal cannabis for supply under 'approved access' provisions (//www.tga.gov.au/publication/manufacture-medicinal-cannabis-supply-under-approved-access-provisions). You will probably require a TGA licence to manufacture (//www.tga.gov.au/publication/guidance-licensingcertification-inspections) in Australia.

Applications for ODC and TGA licences to manufacture

The application processes for the ODC manufacture licence for medicinal cannabis and the TGA licence to manufacture therapeutic goods are separate because they are based on different legislation:

- An ODC manufacture licence manages security, prevention of diversion and control on stock levels, which are obligations on Australia under the Single Convention on Narcotic Drugs 1961.
- A TGA manufacturing licence ensures, through the application of Good Manufacturing Practice, that the medicinal cannabis products will be of appropriate quality.

As a result, the applicable requirements are different. To be granted both licences, the applicant needs to meet both sets of requirements.

Distribution of Australian product

As a controlled drug, the distribution of medicinal cannabis is regulated by the states and territories.

Research

Research (laboratory and nonclinical)

If you want to conduct laboratory or nonclinical research using medicinal cannabis that **does not involve administration to humans**, then the medicinal cannabis can be supplied directly to you from a cultivator/producer. (It does not have to come from a manufacturer.) However, in order for the cultivator

to obtain a licence and permit to supply you with cannabis, they will need to be able to clearly explain to ODC the purpose of the research (https://www.odc.gov.au/cultivators) and the controls that will be in place to prevent illicit use or diversion. These controls will still be required in the conduct of the laboratory or nonclinical research.

You still need to ensure that you have the appropriate permission from your state or territory.

You are not required to hold any licences under the Therapeutic Goods Act unless you are developing a therapeutic good.

Clinical trials

The Therapeutic Goods Act and state and territory legislation apply to clinical trials of medicinal cannabis.

If you wish to conduct a clinical trial using medicinal cannabis:

- Make sure that medicinal cannabis is not a prohibited substance in your state or territory
- Obtain approval from a Human Research Ethical Committee
- Notify the TGA (clinical trial notification scheme) or apply for approval (clinical trial exemption scheme). See Clinical trials at a glance (//www.tga.gov.au/clinical-trials-glance).

If medicinal cannabis for clinical trials comes from an Australian manufacturer, the manufacturer will need to establish a formal relationship with you so that all of the relevant permits can be granted to the manufacturer, producer and cultivator.

Export

Export of medicinal cannabis is currently not permitted under the Narcotic Drugs Act unless the product is on the Australian Register of Therapeutic Goods (ARTG). Export of other medicinal cannabis products may only be considered by Government when this is consistent with our international obligations under the United Nations Single Convention on Narcotic Drugs 1961.

Related guidance

We have prepared a Medicinal cannabis factsheet (pdf,342kb) (http://www.health.gov.au/internet/ministers/publishing.nsf/Content/546FB9EF48A2D570CA257EE1000B98F2/$File/Medicinal-cannabis-factsheet.pdf).

The following guidance on medicinal cannabis as a therapeutic good is available:

- Final decision on scheduling of cannabis and tetrahydrocannabinols (//www.tga.gov.au/final-decision-scheduling-cannabis-and-tetrahydrocannabinols-frequently-asked-questions)
- GMP compliance for the manufacture of medicinal cannabis for supply under 'approved access' provisions (//www.tga.gov.au/publication/manufacture-medicinal-cannabis-supply-under-approved-access-provisions)

- Access to medicinal cannabis products (//www.tga.gov.au/access-medicinal-cannabis-products)
- Access to unapproved therapeutic goods - Clinical trials in Australia (//www.tga.gov.au/publication/access-unapproved-therapeutic-goods-clinical-trials-australia)
- Import and export of controlled substances (//www.tga.gov.au/import-and-export-controlled-substances)

The following guidance on medicinal cannabis as a controlled substance is available:

- medicinal cannabis (https://www.odc.gov.au/medicinal-cannabis)
- cultivation of medicinal cannabis (https://www.odc.gov.au/cultivators)
- manufacture of medicinal cannabis (https://www.odc.gov.au/manufacturers-1)
- import and export of medicinal cannabis (https://www.odc.gov.au/import-and-export)
- questions and answers on medicinal cannabis (https://www.odc.gov.au/qa)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory guidance team	October 2016
V1.1	Update to include reference to TGO 93	Regulatory guidance team	March 2017

Category: Medicinal cannabis
URL: https://www.tga.gov.au/node/732376 (//www.tga.gov.au/medicinal-cannabis-products-overview-regulation)