



**Australian Government**  

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**Department of Health**  
Therapeutic Goods Administration

## Access to medicinal cannabis products

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**31 October 2016**

This guidance is for consumers, health professionals and [sponsors](http://www.tga.gov.au/role-sponsor) that are involved in providing appropriate patients with access to medicinal cannabis products as an unapproved drug through the Special Access Scheme (SAS) or Authorised Prescriber Scheme.

The term 'medicinal cannabis products' covers a range of cannabis preparations intended for therapeutic use, including pharmaceutical cannabis preparations, such as oils, tinctures and other extracts.

The Australian Government is facilitating access to medicinal cannabis products to appropriate patients for medical conditions where there is evidence to support its use. However, to fully achieve this, a number of legislative and regulatory changes have been made or are in the process of being implemented (see the

[Medicinal cannabis factsheet \(pdf,342kb\)](#)

([http://www.health.gov.au/internet/ministers/publishing.nsf/Content/546FB9EF48A2D570CA257EE1000B98F2/\\$File/Medicinal-cannabis-factsheet.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/546FB9EF48A2D570CA257EE1000B98F2/$File/Medicinal-cannabis-factsheet.pdf)) for further information). Additionally, the rules relating to medicinal cannabis products may vary between states and territories and could affect access in those jurisdictions.

Commonwealth Department of Health regulates medicinal cannabis products through the TGA and the [Office of Drug Control \(ODC\)](#) (<https://www.odc.gov.au/medicinal-cannabis>).

Medicinal cannabis products are regulated as medicines in Australia. Generally, medicines imported into, supplied in, and exported from Australia must be entered in the [Australian Register of Therapeutic Goods \(ARTG\)](#) (<http://www.tga.gov.au/australian-register-therapeutic-goods>), which is administered by the TGA. However, there are other mechanisms for approval (or exemption). Medicinal cannabis products supplied in Australia will use these alternative supply pathways while evidence to support registration is gathered through clinical trials.

Legislation came into effect on 30 October 2016 to allow legal cultivation, production and manufacturing of medicinal cannabis products in Australia. This scheme is administered by the ODC. This legislation is designed to make available medicinal cannabis products and works together with the therapeutic goods legislation and state and territory legislation to make medicinal cannabis products [available to certain patients](#).

For further information about legislation and regulation that applies to medicinal cannabis products see our '[Medicinal cannabis products: overview of regulation](http://www.tga.gov.au/medicinal-cannabis-products-overview-regulation)' web page.

**Please note**

Cannabis remains a highly regulated drug in Australia and the use and supply of cannabis for non-medical purposes (for example, recreational use) is illegal in Australia, in accordance with applicable Commonwealth, state and territory laws.

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## Role of the TGA

We administer the *Therapeutic Goods Act 1989* (<https://www.legislation.gov.au/Series/C2004A03952>) (the Act), which establishes the regulatory framework for all medicines in Australia.

The Act provides a number of mechanisms to enable access to unapproved therapeutic goods. For medicinal cannabis products these include:

- access for individual patients through either:
  - [Authorised Prescriber Scheme](http://www.tga.gov.au/form/authorised-prescribers) (<http://www.tga.gov.au/form/authorised-prescribers>)
  - [Special Access Scheme](http://www.tga.gov.au/form/special-access-scheme) (<http://www.tga.gov.au/form/special-access-scheme>) (Category B)
- access as part of a [clinical trial](http://www.tga.gov.au/clinical-trials) (<http://www.tga.gov.au/clinical-trials>).

These mechanisms maintain the same standards for medicinal cannabis products that apply to any other experimental or emerging medicine.

We also play a role in the [scheduling of medicines](http://www.tga.gov.au/scheduling-basics) (<http://www.tga.gov.au/scheduling-basics>). However, the states and territories have the authority to decide if they want to adopt a scheduling change for a medicine in their relevant legislation.

Down scheduling of medicinal cannabis products from Schedule 9 (S9) Prohibited Substances to Schedule 8 (S8) Controlled Drug in certain circumstances takes effect from 1 November 2016. When states and territories choose to implement this scheduling decision into the relevant law in their jurisdictions, the number of restrictions placed on their manufacture, supply, possession and use, will be reduced to facilitate access to appropriate patients.

The 1 November version of the [Poisons Standard](http://www.tga.gov.au/publication/poisons-standard-susmp) (<http://www.tga.gov.au/publication/poisons-standard-susmp>) provides more detail on the scheduling requirements and the [Explanatory Memorandum](https://www.legislation.gov.au/Details/F2016L01505/Explanatory%20Statement/Text) (<https://www.legislation.gov.au/Details/F2016L01505/Explanatory%20Statement/Text>) has further explanation.

While TGA is responsible for the regulation of the quality aspects of medicinal cannabis products, we are not responsible for the regulation of domestic cultivation and harvest of medicinal cannabis. Cultivation and harvest, as well as other aspects of manufacture are regulated in the *Narcotics Drug Act 1967*, which is administered by the [ODC](https://www.odc.gov.au/medicinal-cannabis) (<https://www.odc.gov.au/medicinal-cannabis>).

## Accessing medicinal cannabis products

We administer the following schemes that allow eligible medical practitioners to apply for the importation and supply of medicinal cannabis products that are not registered on the ARTG:

- [Authorised Prescriber Scheme](http://www.tga.gov.au/form/authorised-prescribers) (<http://www.tga.gov.au/form/authorised-prescribers>)

- [Special Access Scheme \(//www.tga.gov.au/form/special-access-scheme\)](https://www.tga.gov.au/form/special-access-scheme) (Category B).

While there are additional legal requirements that must be met before medicinal cannabis products can be imported and supplied through these schemes, they do provide a pathway for access to these medicines to appropriate patients.

We also allow access for the purposes for clinical trials, which may be conducted to develop an evidence base to support safety and efficacy of medicines. For further information see our '[Clinical trials at a glance \(//www.tga.gov.au/clinical-trials-glance\)](https://www.tga.gov.au/clinical-trials-glance)' web page.

## **Information for consumers**

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Individual consumers cannot apply to us to obtain approval to import and access unapproved medicinal cannabis products.

Such access can only be arranged through an Australian registered medical practitioner (a doctor) with appropriate qualifications and/or expertise for the medical condition requiring treatment. This doctor should first obtain approval under the applicable state or territory laws to prescribe a medicinal cannabis product to a particular patient. Please note that the rules relating to medicinal cannabis products may vary between states and territories and could affect whether or not you can be prescribed those medicines in that jurisdiction.

Subsequently, the doctor can apply on the patient's behalf for approval to import and supply these products through the Special Access Scheme (SAS). Alternatively, the doctor can apply to us to become an Authorised Prescriber. Approval or authorisation is granted on a case-by-case basis.

Additionally, if approved, the doctor (or pharmacist/hospital on the doctor's behalf) wishing to import the product will then need to [obtain import permits from the ODC \(https://www.odc.gov.au/importers-exporters-travellers\)](https://www.odc.gov.au/importers-exporters-travellers).

We are developing educational materials in consultation with the states and territories for doctors to support them in determining whether prescribing medicinal cannabis is appropriate and beneficial. These educational materials will also provide more detailed information on how to use the available access schemes (such as what supporting documentation will be required).

For answers to frequently asked questions relating to accessing medicinal cannabis products see the consumer section of our '[Access to medicinal cannabis products: questions and answers \(//www.tga.gov.au/access-medicinal-cannabis-products-questions-and-answers\)](https://www.tga.gov.au/access-medicinal-cannabis-products-questions-and-answers)' web page.

If you have any other questions about medicinal cannabis products, talk to your doctor.

## **Information for health professionals**

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Australian registered medical practitioners who want to access medicinal cannabis products for the treatment of appropriate patients outside of clinical trials may choose to do so through the [SAS \(//www.tga.gov.au/form/special-access-scheme\)](https://www.tga.gov.au/form/special-access-scheme) (Category B) or the [Authorised Prescriber Scheme \(//www.tga.gov.au/form/authorised-prescribers\)](https://www.tga.gov.au/form/authorised-prescribers).

If you are an Australian registered medical practitioner wanting to access medicinal cannabis products for your patient(s) through the above schemes, you should follow these steps:

**Step 1:** Determine your state/territory legislative requirements

**Step 2:** Make an application under the SAS (Category B) or the Authorised Prescriber Scheme

**Step 3:** Apply for a licence and permission to import, if necessary

**Step 4:** Comply with conditions of approval/authorisation and ongoing regulatory requirements

For further information regarding these processes see our '[Access to medicinal cannabis products: steps to using access schemes](https://www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes)' web page.

For answers to frequently asked questions relating to accessing medicinal cannabis products see the health professional section of our '[Access to medicinal cannabis products: questions and answers](https://www.tga.gov.au/access-medicinal-cannabis-products-questions-and-answers)' web page.

## **Information for sponsors and manufacturers of medicinal cannabis products**

The person or company in Australia who provides the unapproved medicinal cannabis product to the treating medical practitioner or pharmacist is considered the sponsor of that product in Australia. In cases where the medicinal cannabis product is sourced from overseas, the sponsor may also be the importer of the medicine.

The Act outlines the legal responsibilities of the sponsor of unapproved medicinal cannabis products, as follows:

- Ensure compliance with all applicable standards - there are a number of Therapeutic Goods Orders that apply to medicinal cannabis products. Civil and criminal penalties may apply where these requirements are not met. Non-compliance with a standard is also grounds for recalling a medicine from the market.
- The sponsor importing the medicinal cannabis product is not legally able to supply the product until the product has received all of the relevant approvals, authorisation or exemption. Supplying a product without the relevant approval, authorisation or exemption would amount to unlawful supply. Civil and criminal penalties may apply in such circumstances.

### **Product quality standards**

Therapeutic goods must comply with various product quality standards. There are various standards that may apply to your medicinal cannabis product, e.g. microbiological content, tablet and capsule quality, contamination, etc. These apply to medicinal cannabis products imported into Australia as well as those manufactured in Australia.

### **Manufacturing standards**

A licence to manufacture therapeutic goods (if domestic) or a Good Manufacturing Practice (GMP) clearance (if overseas) is required unless exempted in Schedule 7 or Schedule 8 of the [Therapeutic Goods Regulations 1990](https://www.legislation.gov.au/Series/F1996B00406). The applicable standard for medicines manufacture is the [Code of GMP](https://www.tga.gov.au/good-manufacturing-practice-overview). This standard applies to both Australian and overseas medicines manufacturers, including manufacturers of medicinal cannabis products. We have published specific [guidance on GMP compliance for the manufacture of medicinal cannabis products](https://www.tga.gov.au/publication/manufacture-medicinal-cannabis-supply-under-approved-access-provisions) in these exempted situations for supply under 'approved access' provisions.

Evidence that the medicinal cannabis product has been manufactured in accordance with the Code of GMP (or, for overseas manufacturers, an equivalent manufacturing standard) should be available and provided to the medical practitioner to support his/her application.

## **Reporting requirements**

### **Import and supply**

Reporting requirements for the import and supply of unapproved therapeutic goods may apply to both the sponsor of the goods and the person to whom approval has been granted (the medical practitioner or pharmacist).

The responsibilities of the sponsor supplying therapeutic goods under the SAS or the Authorised Prescriber Scheme are set out in Schedule 5A item 1 of the Therapeutic Goods Regulations 1990 (<https://www.legislation.gov.au/Series/F1996B00406>).

The sponsor is required to submit a report to us every six months listing the therapeutic goods supplied to medical practitioners under the SAS or the Authorised Prescriber Scheme.

The report by the sponsor must list each of the unapproved therapeutic goods supplied by the sponsor during the period to which the report relates; and state the number of times these therapeutic goods have been supplied to medical practitioners, and the quantity supplied.

Therefore the sponsor should submit a report twice yearly (for example, at the end of June and December) detailing the number of times the therapeutic goods have been supplied and the quantity supplied.

### **Adverse events**

In relation to the supply of therapeutic goods under the SAS or the Authorised Prescriber Scheme, the sponsor has a role in monitoring the use of their products continually and to record the safety of the medicine and the balance of its benefit and risk.

Ideally, the use of an unapproved therapeutic good should be the subject of treatment protocols issued by the sponsor, with clear requirements for the treating medical practitioner to report any adverse outcomes to the sponsor.

Sponsors of therapeutic goods supplied under the SAS or the Authorised Prescriber Scheme are also required to communicate rapidly to the TGA information that has an important bearing on the benefit-risk assessment of the product, particularly if it may lead to changes to the usage under the schemes.

Sponsors are required to report adverse events within the timeframes outlined in the guidelines Access to unapproved therapeutic goods via the Special Access Scheme ([//www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme](http://www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme)) and Access to unapproved therapeutic goods: Authorised prescribers ([//www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers](http://www.tga.gov.au/access-unapproved-therapeutic-goods-authorised-prescribers)), respectively.

For more information on how to report adverse events, please see the 'How to submit an adverse event report' ([//www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes#step4-adverse](http://www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes#step4-adverse)).

## **Supporting documentation to be provided by medical practitioners**

An application to access unapproved medicinal cannabis products can be made under the SAS (Category B) and the Authorised Prescriber Scheme by a medical practitioner.

Medical practitioners are required to complete the relevant application form and provide supportive information in relation to the product to allow us to assess if the import and/or supply of the medicinal cannabis product is appropriate.

Further information can be found under 'Evidence to accompany the application to access medicinal cannabis products' in [Step 2 of the 'Access to medicinal cannabis products: steps to using access schemes' \(//www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes#step2\)](#) web page.

For answers to frequently asked questions relating accessing medicinal cannabis products, see the sponsors of medicinal cannabis products section of ['Access to medicinal cannabis products: questions and answers' \(//www.tga.gov.au/access-medicinal-cannabis-products-questions-and-answers\)](#).

## Further information

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Further information on the various access requirements for medicinal cannabis is available from:

- [Access to medicinal cannabis products: questions and answers \(//www.tga.gov.au/access-medicinal-cannabis-products-questions-and-answers\)](#)
- [Access to medicinal cannabis products: steps to using access schemes \(//www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes\)](#)
- [Medicinal cannabis products: overview of regulation \(//www.tga.gov.au/medicinal-cannabis-products-overview-regulation\)](#)
- [Special Access Scheme \(SAS\) \(//www.tga.gov.au/form/special-access-scheme\)](#)
- [Authorised prescribers \(//www.tga.gov.au/form/authorised-prescribers\)](#)
- [Import and export of controlled substances \(//www.tga.gov.au/import-and-export-controlled-substances\)](#)
- [TGA - import and supply of therapeutic goods \(//www.tga.gov.au/import-and-export\)](#)
- [Medicinal cannabis factsheet \(pdf,342kb\) \(http://www.health.gov.au/internet/ministers/publishing.nsf/Content/546FB9EF48A2D570CA257EE1000B98F2/\\$File/Medicinal-cannabis-factsheet.pdf\)](#)
- [Final decision on scheduling of cannabis and tetrahydrocannabinols \(//www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-cannabis-and-tetrahydrocannabinols-march-2016\)](#)
- [Scheduling decision FAQ \(//www.tga.gov.au/final-decision-scheduling-cannabis-and-tetrahydrocannabinols-frequently-asked-questions\)](#)
- [Office of Drug Control \(https://www.odc.gov.au\)](#)
- [Office of Drug Control - permits and licences to import \(https://www.odc.gov.au/licence-and-permit-application-forms\)](#)
- [states and territories - possession, sale and use of drugs and poisons scheduling](#)

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**URL:** <https://www.tga.gov.au/node/732373> ([//www.tga.gov.au/access-medicinal-cannabis-products](https://www.tga.gov.au/access-medicinal-cannabis-products))

