Australian Government
Department of Health
Therapeutic Goods Administration

# Access to medicinal cannabis products

**23 March 2017**

This guidance is for consumers, health professionals, sponsors and maufacturers (//www.tga.gov.au/role-sponsor) who 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 implemented at the Commonwealth level . 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 (//www.tga.gov.au/australian-register-therapeutic-goods) (ARTG), which is administered by the TGA. However, there are other mechanisms for access to medicines that are not registered on the ARTG . 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 (//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-medicinal 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 (//www.tga.gov.au/form/authorised-prescribers)
  - Special Access Scheme (//www.tga.gov.au/form/special-access-scheme) (Category B)
- access as part of a clinical trial (//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 (//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 came into effect on 1 November 2016. It is a matter for the states and territories to implement this scheduling decision into the relevant law in their jurisdictions to reduce the number of restrictions placed on their manufacture, supply, possession and use, to facilitate access to appropriate patients.

The 1 November 2016 version of the Poisons Standard (//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) has further explanation.

The TGA is responsible for the regulation of the quality aspects of medicinal cannabis products.

The *Therapeutic Goods Order No. 93 - Standard for Medicinal Cannabis (https://www.legislation.gov.au/Details/F2017L00286)* (TGO 93) has been developed by the TGA, after consultation with stakeholders, to provide appropriate regulatory controls to ensure that the quality of the medicinal cannabis products and ingredients used in the manufacture of medicinal cannabis products is acceptable.

The ODC is responsible for the regulation of domestic cultivation and harvest, as well as other aspects of manufacture of medicinal cannabis, under the *Narcotics Drug Act 1967*.

## 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 (//www.tga.gov.au/form/authorised-prescribers)
- Special Access Scheme (//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 of 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)' web page.

## Information for consumers

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 apply and 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 both state and TGA approval requirements are satisfied, 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).

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)' web page.

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

## Information for health professionals

Australian registered medical practitioners who want to access unapproved 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) (Category B) or the Authorised Prescriber Scheme (//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 may need to do or arrange the following:

- determine your state/territory legislative requirements
- make an application under the SAS (Category B) or the Authorised Prescriber Scheme
- apply for a licence and permission to import, if necessary
- comply with conditions of approval/authorisation and ongoing regulatory requirements.

For further information regarding these processes, including a step-by-step resource for doctors, please see our 'Access to medicinal cannabis products: steps to using access schemes (//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 (//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

Sponsors of medicinal cannabis products must ensure that their products comply with all applicable quality standards. There are various standards that may apply to medicinal cannabis products, including *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) (TGO 93) (https://www.legislation.gov.au/Details/F2017L00286)*.

TGO 93 applies to:

- approved and unapproved medicinal cannabis products
- imported and Australian manufactured medicinal cannabis products
- medicinal cannabis products supplied in Australia or exported from Australia (//www.tga.gov.au/medicinal-cannabis-products-overview-regulation#export).

The TGA has published a guidance document (//www.tga.gov.au/conforming-tgo-93-standard-medicinal-cannabis) that provides a plain English explanation of various requirements of TGO 93 and their application to assist sponsors in complying with their regulatory obligations.

The TGA has developed a declaration form (//www.tga.gov.au/form/medicinal-cannabis-products) that must be completed for unapproved medicinal cannabis products to declare that the product(s) conform to TGO 93. This should be completed by the medicinal cannabis product manufacturer.

The reason for requesting that the medicinal cannabis product manufacturer complete the declaration form (//www.tga.gov.au/form/medicinal-cannabis-products) is that the **person** importing or supplying the unapproved medicinal cannabis product(s) in Australia may not be the **commercial sponsor** of the good (e.g., a medical practitioner). The highly technical nature of TGO 93 means that this person may not be in a position to declare that the product conforms to the standard. The manufacturer of the medicinal cannabis product that has responsibility for quality control testing of the finished product is best placed to declare that the medicinal cannabis product conforms to this standard.

The manufacturer of the medicinal cannabis product(s) is required to submit the completed form to the person applying to access the medicinal cannabis product(s) through the available access pathways.

For unapproved medicinal cannabis products to be accessed via:

- **SAS B and Authorised Prescriber:** The form is submitted to the medical practitioner. The medical practitioner is required to submit this form as supportive documentation to the TGA with their application.
- **Clinical Trials - CTN/CTX:** The form is submitted to the clinical trial sponsor. The Australian clinical trial sponsor should complete the section at the end of the form to include the name of the medicinal cannabis product(s) used in the clinical trial as well as the TGA clinical trial application number and protocol number. The clinical trial sponsor is then required to submit this form as supportive documentation to the TGA with their application or notification, as applicable. In the case of a CTN involving the use of a medicinal cannabis product, the clinical trial sponsor should submit this form via email to clinical.trials@health.gov.au (mailto:clinical.trials@health.gov.au). In the case of a CTX involving the use of a medicinal cannabis product, the clinical trial sponsor should submit this form as part of the CTX application made to the TGA.

Please note that although the cannabis plant used in the manufacture of the medicinal cannabis product must meet the requirements of Schedule 1 of TGO 93, reduced or rotational testing of the cannabis plant used in the manufacture of the product can be carried out provided that this is justified on good manufacturing practice (GMP) grounds. For example, a manufacturer may be able to justify reducing or not conducting pesticide testing if no pesticides are used in the cultivation of the cannabis plant. The manufacturer should ensure that the product, if tested by the TGA laboratories, will meet all the requirements of the standard.

### Manufacturing standards

Australian medicines manufacturers are required to obtain a licence to manufacture medicinal cannabis products (sometimes referred to as GMP licence) unless exempted in Schedule 7 or Schedule 8 of the *Therapeutic Goods Regulations 1990 (https://www.legislation.gov.au/Series/F1996B00406)*. This requirement applies to products that are on the ARTG and unapproved products that may be accessed through the available pathways for medicinal cannabis products. The applicable standard for medicines manufacture is the Code of GMP (//www.tga.gov.au/good-manufacturing-practice-overview). We have published specific guidance on GMP

compliance for the manufacture of medicinal cannabis products (//www.tga.gov.au/publication/manufacture-medicinal-cannabis-supply-under-approved-access-provisions) that applies to unapproved products supplied under 'approved access' provisions.

For medicinal cannabis products intended to be registered on the ARTG that involve an overseas manufacturer, evidence of acceptable GMP in the form of a GMP clearance will be required for each of the overseas manufacturing sites before the goods can be registered. A GMP clearance is only issued if robust evidence is provided to demonstrate that the medicinal cannabis product has been manufactured in accordance with the Code of GMP (or an equivalent manufacturing standard). For more information on how to obtain a GMP clearance please see GMP clearance for overseas manufacturers (//www.tga.gov.au/publication/gmp-clearance-overseas-manufacturers).

For medicinal cannabis products intended to be supplied through the available unapproved medicine access pathways that involve an overseas manufacturer, evidence that the medicinal cannabis product has been manufactured in accordance with an acceptable manufacturing standard should be available and provided on request to the TGA.

## 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) and Access to unapproved therapeutic goods: Authorised prescribers (//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)'.

### Supporting documentation to be provided by medical practitioners

An application to access unapproved medicinal cannabis products can be made under the SAS (Category B) or 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 and manufacturers 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

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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