Australian Government
Department of Health
Therapeutic Goods Administration

# Access to medicinal cannabis products: steps to using access schemes

**31 October 2016**

The following steps outline the requirements for an Australian registered medical practitioner to access medicinal cannabis products through the Special Access Scheme (SAS) (//www.tga.gov.au/form/special-access-scheme) and the Authorised Prescriber Scheme (//www.tga.gov.au/form/authorised-prescribers).



## 1. Determine your state / territory regulatory requirements

In most states and territories in Australia, approval or permission is required by a medical practitioner in order to prescriber medicinal cannabis products to their patient(s).

Additionally, particular medicinal cannabis products may be scheduled differently under the Schedule of Medicines and Poisons (//www.tga.gov.au/publication/poisons-standard-susmp) (SUSMP or 'Poisons Standard'). The adoption of the SUSMP may vary between different states and territories.

The medical practitioner should provide evidence of the relevant state/territory approvals to prescribe a particular medicinal cannabis product for the particular patient, noting that these may vary depending on the scheduling and between jurisdictions.

Contact the relevant state or territory medicinal cannabis area in your state or territory health department for further information.

- 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)
- VIC Department of Health and Human Services (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/)

### Scheduling of medicinal cannabis products

Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into schedules according to the level of regulatory control that is required to protect public health and safety.

In some jurisdictions, the scheduling of medicinal cannabis products will determine the requirements under the state or territory drugs and poisons legislation.

The scheduling of medicinal cannabis products predominantly containing cannabidiol is dependent on the concentration of other cannabinoids found in cannabis that are in the product.

Medical practitioners seeking to access cannabidiol products in Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard should liaise with the supplier of the product to ensure that the maximum limit applied to all other cannabinoids are such that the variability within and between batches to be supplied allow it to remain within that schedule.

The addition of an entry in Appendix D of the Poisons Standard as part of the recent scheduling decision means that medical practitioners must be approved by their state/territory health department before they can prescribe medicinal cannabis products in that jurisdiction. The legislation between each state and territory may be different and a medical practitioner should ensure they meet the applicable prescribing requirements before applying to the TGA.

#### Cannabis and tetrahydrocannabinols

Under certain circumstances (//www.tga.gov.au/book-page/part-final-decision-matter-referred-expert-advisory-committee#s11), cannabis (including seeds, extracts, resins and the plant or any part of the plant) and tetrahydrocannabinols (when extracted from cannabis) when prepared or packed for human therapeutic use, are 'Controlled Drugs' under Schedule 8 (S8) of the Poisons Standard (//www.tga.gov.au/publication/poisons-standard-susmp).

Access in the particular state/territory will need to be confirmed with the state/territory.

#### Cannabidiol

Cannabidiol (CBD) is one of the cannabinoids which may be extracted as a therapeutic good from cannabis. From 1 June 2015, cannabidiol has been included under Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard (//www.tga.gov.au/publication/poisons-standard-susmp) when preparations for therapeutic use contain 2% or less of other cannabinoids found in cannabis.

#### Other substances

Nabiximols, nabilone and dronabinol are listed as Controlled Drugs in S8 of the Poisons Standard (//www.tga.gov.au/publication/poisons-standard-susmp). S8 substances also require a prescription from an Australian-registered medical practitioner to obtain and possess within Australia.

For further information regarding the recent scheduling decision, please refer to Final decision on scheduling of cannabis and tetrahydrocannabinols: Frequently asked questions (//www.tga.gov.au/final-decision-scheduling-cannabis-and-tetrahydrocannabinols-frequently-asked-questions).

## 2. Make an application under the SAS (Category B) or the Authorised Prescriber Scheme

The SAS refers to arrangements that provide for the import and/or supply of therapeutic goods not entered on the ARTG for a single patient. A new SAS approval is required for each patient and on the expiry of a previous SAS approval if granted.

Under the Authorised Prescriber Scheme, the TGA is able to grant medical practitioners authority to prescribe a specified therapeutic good or class of therapeutic goods to specified recipients or classes of recipients. Approval from an appropriate Human Research Ethics Committee (HREC) (//www.tga.gov.au/obtaining-endorsement-ethics-committee) must be submitted to the TGA as part of a medical practitioner's application (specialist college endorsement may be acceptable where the medical practitioner does not have access to a HREC).

Further information and forms can be obtained from the Special Access Scheme (SAS) (//www.tga.gov.au/form/special-access-scheme) and Authorised prescribers (//www.tga.gov.au/form/authorised-prescribers) web pages.

Medical practitioners applying to access medicinal cannabis products for their patients should review Special Access Scheme applications (//www.tga.gov.au/form/special-access-scheme#about) and How to become an Authorised Prescriber (//www.tga.gov.au/4031) web pages to assist in the application/notification processes.

The application form for SAS (Category B) (//www.tga.gov.au/form/special-access-scheme#forms) can be accessed from this website.

The application form ('Agreement to Treatment Directions') for the Authorised Prescriber Scheme (//www.tga.gov.au/form/authorised-prescribers) can be accessed from this website.

### Evidence to accompany the application to access medicinal cannabis

Medical practitioners applying to access medicinal cannabis products for their patients under the SAS (Category B) and the Authorised Prescriber Scheme must provide information to satisfy the criteria around the patient, product and prescriber, consistent with the principles described 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.

#### Patient (or in the case of Authorised Prescriber, class of patients)

An application from a medical practitioner to access medicinal cannabis products must be accompanied by clinical evidence. This clinical evidence should accompany a justification that discusses the use of the product for the proposed indication. This allows TGA to make an assessment of potential benefits and harms for the indication for which it will be used in the proposed patient or class of patients.

The efficacy and safety data submitted in support of the application should be weighed against the seriousness of the condition. As a general rule, the less critical the clinical need for the proposed product, the higher the degree of evidence needed to support the use of that product.

It will also be expected that approved standard medicine or non-medicine treatments have already been used for the patient; or that evidence is provided to demonstrate that the available alternatives are not appropriate for the treatment of the named patient.

For repeat applications to access medicinal cannabis for the same patient to treat the same indication, the medical practitioner is expected to provide evidence of positive benefit to risk to support the continued use of the medicinal cannabis product for the patient as part of the supportive information.

#### Prescriber

The medical practitioner must have appropriate qualifications and/or expertise for the proposed indication(s) relevant to the product being proposed for use.

If the medicinal practitioner is not a specialist in the condition to be treated with the medicinal cannabis product, then the TGA would expect a specialist report from an appropriate specialist on the use and suitability of the product for the particular indication for the patient requested to be sent by your doctor as part of their application.

#### Product

The product must be legally produced, either in Australia or overseas, and manufactured using appropriate manufacturing quality standards and to the relevant quality standards.

The sponsor (//www.tga.gov.au/role-sponsor) is responsible for ensuring compliance with these standards. Information for sponsors of medicinal cannabis products can be found at: Access to

medicinal cannabis products - Information for sponsors and manufacturers (//www.tga.gov.au/access-medicinal-cannabis-products#sponsors).

Prior to lodging an application to access a medicinal cannabis product through the above schemes, you must have identified a specific therapeutic good from a known sponsor who is able to legally export and/or supply the good in Australia. The sponsor should also provide you with all the following necessary information required to support the application.

The following information on the proposed product should accompany the application:

| **Information** | **Description** |
|---|---|
| Trade name | The brand name of the product as displayed on the product label. |
| Formulation | The name, strength and concentration of each active ingredient and excipient(s) in the finished product. |
| Dosage form | The pharmaceutical form in which a product is presented for therapeutic administration, for example tablet, capsule, liquid oil. |
| Name of the sponsor (//www.tga.gov.au/role-sponsor) | The name of the sponsor of the good. |
| Schedule of the medicinal cannabis product | See: Scheduling of medicinal cannabis products |
| Route of administration | Route by which the medicinal cannabis product will be applied on or introduced into the body, for example topical, oral, inhalation. |
| Shelf life of the product | The time period during which a therapeutic good is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label. Include details of both closed and open (or in-use) shelf-life (as applicable).<br>The TGA expects the shelf life of the product to be established in accordance with the principles outlined in the relevant International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance documents adopted by the TGA (//www.tga.gov.au/quality-guidelines). |

| Information | Description |
|---|---|
| Finished Product Specifications (FPS) and/or Certificate of Analysis (COA) | These documents demonstrate that the product has been manufactured in accordance with acceptable quality standards that apply to medicines, and in the case of cannabidiol, it will determine the scheduling status of the medicine. See further information on Finished Product Specifications (FPS) and/or Certificate of Analysis (COA) below*. |
| Ancillary dosing aids (if applicable) | Include details of any supplementary devices which may be needed to allow the dose to be appropriately administered, for example syringes or vaporising devices. |

#### *Finished Product Specifications (FPS) and/or Certificate of Analysis (COA)

The trade name, active ingredients and dose form should concur with the FPS and/or COA provided with the application.

The FPS is the set of tests and limits applicable to the finished product in order to ensure that every batch is of satisfactory and consistent quality at release and throughout its shelf life. The specifications should include all critical parameters in which variations would be likely to affect the quality of the product.

The COA is a document that confirms that a regulated product meets its finished product specifications.

The laboratory COA or FPS should be provided as part of the SAS or Authorised Prescriber application for all medicinal cannabis products, as this serves to demonstrate that the product has been manufactured in accordance with acceptable quality standards that apply to medicines, and in the case of cannabidiol it will determine the scheduling status of the medicine.

This will ensure that only medicinal cannabis of a high quality is delivered to patients and the relevant state/territory approvals have been obtained.

The medical practitioner is required to obtain this information from the sponsor of the product.

The TGA is developing quality standards that provide information on the quality requirements for medicinal cannabis products. This will apply to medicinal cannabis products imported into Australia and products manufactured in Australia.

For medicinal cannabis products intended to be administered via the inhalation route, the TGA expects the applicant to provide evidence demonstrating that the delivered dose can be reproducibly delivered to the patient and that the temperature applied to the cannabis is high enough to allow for active cannabinoid vapors to form, but below the point of combustion where smoke and associated toxins are produced.

#### Devices to administer certain medicinal cannabis products

For products to be administered via inhalation through a vaporising device, medical practitioners should note that there are currently no vaporising devices included on the ARTG to be used for medicinal cannabis.

A vaporising device can be obtained through the unapproved medical device access pathways, which also include the Authorised Prescriber Scheme, SAS (Category B) and the Personal Importation Scheme (//www.tga.gov.au/personal-importation-scheme).

It should be noted that if a medicinal cannabis product for inhalation is approved under the SAS or the Authorised Prescriber Scheme, this approval would be conditional on use with an appropriate medical device.

## 3. Apply for a licence and permission to import, if necessary

Cannabis, cannabis resin, extracts, oils and tinctures of cannabis, and cannabinoids (including cannabidiol and tetrahydrocannabinols) are captured under the *Customs (Prohibited Imports) Regulations 1956 (https://www.legislation.gov.au/Series/F1996B03651)*. A licence and permission to import is required prior to importing any product containing these substances.

A medical practitioner, or pharmacist acting on behalf of the medical practitioner, can apply for a licence and permission to import (//www.tga.gov.au/import-and-export-controlled-substances). Note that a commercial sponsor may also apply for a licence and permission to import for supply under SAS.

A medical practitioner, or pharmacist, should provide as part of an application for a licence and permission to import:

- state/territory approval (if applicable)
- an approval or authorisation under the SAS or Authorised Prescriber Scheme
- a FPS or COA for the product to be imported.

A commercial sponsor who intends to supply medicinal cannabis under the exemption under Schedule 5A, item 1 of the Therapeutics Goods Regulations 1990 is required to provide, with their application for a licence and permission to import, their state/territory licence and/or approval (if applicable), COA of the product(s) and details of supply.

Licence and permit application forms and guidance (https://www.odc.gov.au/licence-and-permit-application-forms-0) are available on the Office of Drug Control website.

The relevant documentation must be presented to the Australian Border Force (https://www.border.gov.au/australian-border-force-abf) as permission to import the medication into Australia.

Please contact the Office of Drug Control (https://www.odc.gov.au/contact-us) for further information regarding the application process. Contact details are available from Import and export of controlled substances (//www.tga.gov.au/import-and-export-controlled-substances).

## 4. Conditions of approval / authorisation and ongoing regulatory requirements

After a medical practitioner has received approval for import and supply of a medicinal cannabis product for administration by the patient, under either the SAS or the Authorised Prescriber Scheme, there are a number of ongoing requirements with which the medical practitioner must comply. These include following the conditions of any approvals granted, obtaining informed consent and any reporting requirements.

### Conditions of the approval or authorisation

Each approval under either the SAS or the Authorised Prescriber Scheme will be provided with particular conditions relating to that approval.

It is the responsibility of the medical practitioner being provided the approval to ensure the conditions are complied with.

SAS approval conditions may include, but are not limited to:

1. The doctor and patient, patient's parents or guardian accept responsibility for any adverse consequence of therapy.
2. The product is used within the context of fully informed consent and in accordance with the treatment protocol provided to the TGA with the request.
3. The principles set out in the National Health and Medical Research Council's Statement on Human experimentation be observed.
4. Details of any suspected adverse drug reactions are to be reported to the Experimental Products Section of the TGA.
5. The TGA be notified of reasons for discontinuation should this occur.
6. Details of patient response to treatment are submitted to the supplier on completion of treatment ensuring compliance with state, territory and Australian Government privacy legislation.
7. On completion of treatment all remaining supplies of the above product be returned to the supplier or destroyed should no supplier be present in Australia.
8. The person supplying the product accepts responsibility for any defects in the product related to the manufacture, distribution or directions for usage including dosage.

Authorised Prescriber approval conditions may include, but are not limited to:

1. The unapproved therapeutic good can be prescribed only for patients under the authorised medical practitioner's immediate care.
2. The authorised medical practitioner will obtain informed consent from the guardian of each patient in relation to the proposed use of the unapproved therapeutic good.

3. The authorised medical practitioner will report any suspected adverse reaction to the unapproved therapeutic good to the TGA and endorsing Human Research Ethics Committee (HREC).
4. The authorised medical practitioner must continue to have an appropriate endorsement from the HREC in order to continue to supply the product under the authorisation. In the event that the relevant HREC withdraws its endorsement, the authorised medical practitioner must immediately notify the TGA of the date this occurred.
5. The authorised medical practitioner will instruct the patient's guardian to return any unused part of the goods to the authorised prescriber or to a pharmacy for destruction.

The delegate making the decision under either scheme may also choose to approve or authorise the application subject to conditions other than those outlined above.

### Informed consent

The patient or the patient's legal guardian must be in a position to make an informed decision regarding treatment. This informed consent should be obtained from the patient prior to the supply or administration of the good.

In the case of an SAS application, ideally the consent should be sought prior to the application being submitted to the TGA so that the patient is aware that:

- that the product is not approved in Australia and (potentially) other countries
- the possible benefits of treatment and any risks and side effects that are known
- the possibility of unknown risks and late side effects
- any alternative treatments using approved products which are available.

Obtaining this consent prior to submission of the application ensures that process is initiated in good faith with the TGA and that, if approval is granted, the patient would reasonably be expected to be treated with the product in question.

Informed consent should be in writing unless there are good reasons to the contrary.

Informed consent should be freely given and in line with good medical practice, include an adequate knowledge of the condition and its consequences, an adequate knowledge of the treatment options, the likelihood of recovery and the long-term prognosis.

### Reporting requirements (import and supply) - SAS and Authorised Prescriber

There is no current requirement for medical practitioners to report the supply of an individual therapeutic good supplied to a patient approved under the SAS (Category B) form unless it is required by one or more of the conditions given as part of the approval, for example reporting of discontinuation of treatment.

An Authorised Prescriber must provide a report to the TGA on a six monthly basis listing each of

the unapproved therapeutic goods supplied during this period.

The Authorised Prescriber Scheme approval letter is accompanied by a six monthly reporting form, which can serve as a template for reporting. Reports should be emailed to EPS@tga.gov.au (mailto:EPS@tga.gov.au) at the end of each six month period.

Applications for renewal of Authorised Prescriber status will not be considered unless all reports for the previous approval period have been submitted.

### Reporting requirements (adverse event reporting) - SAS and Authorised Prescriber

Adverse events should be reported to the TGA in accordance with the conditions of the approval or authorisation.

Medical practitioners 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' section below.

#### How to submit an adverse event report

Adverse event reports must be submitted to the TGA (//www.tga.gov.au/reporting-problems) using either a CIOMS form, the Adverse event 'blue card' or online reporting form, and can be submitted via mail, facsimile, email or online on the TGA website.

Taking into account the international dimension of adverse event reporting and the need to achieve harmonisation and high quality between all involved parties, adverse event reports should be submitted electronically as structured data with the use of controlled vocabularies for the relevant data elements where applicable.

Reports submitted to the TGA must:

- be legible and easy to read (e.g., in Times or Arial fonts); and
- not be photo-reduced or condensed, allowing the submitted report to be scanned and photocopied.

It is preferable that font size be in ten point font or larger. Reports using a font size less than 10 points should be posted, rather than faxed.

Computer-generated forms are acceptable, provided they are legible and follow the accepted content and layout.

All reports must clearly identify the name and contact details of the person in Australia who is

taking responsibility on behalf of the sponsor for the accuracy and veracity of the information in the report. For sponsors, it is preferable that adverse event reports are submitted by the nominated contact person for pharmacovigilance.

The TGA will advise the sponsor or medical practitioner submitting the adverse event report if it regards a report format to be unacceptable.

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**Category:** Medicinal cannabis
**URL:** https://www.tga.gov.au/node/732375 (//www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes)