

Medicinal Cannabis

Disclaimer

This pathway is about the use of cannabis for medical conditions. For information about screening, dependency, and withdrawal, see [Cannabis Use and Dependence](#).

This pathway covers Victorian regulations. Note rules differ in [other states and territories](#).

Clinical editor's note

Regulations involving medicinal cannabis are rapidly changing. Review current Victorian and Commonwealth regulations at the time of prescribing.

Any medical practitioner can prescribe a medicinal cannabis product for their patient, if they believe it is clinically appropriate to do so.

Key links

[Access to Medicinal Cannabis Products in Australia Flow Chart](#)

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Background

About medicinal cannabis

Composition of Cannabis:

- Botanical marijuana contains a variety of cannabinoids.
 - Tetrahydrocannabinol (THC) is the primary psychotropic cannabinoid found in marijuana and is responsible for most of its psychological effects.
 - Cannabidiol (CBD) is a non-psychoactive cannabinoid which can block the high associated with THC. It has anticonvulsant, muscle relaxant, analgesic, and antiemetic properties.
- A variety of plant-derived and synthetic cannabinoids have been developed for medicinal use.

Regulation:

- Governments at both Commonwealth and state and territory levels have implemented legislative and policy change to allow cultivation, manufacture, prescribing, and dispensing of medicinal cannabis products to patients in Australia.
- Regulations may change in the future.

Assessment

Medicinal cannabis is not considered a first-line therapy for any indication. Consider only when registered medicines have all been tried and proven unsuccessful.

1. Consider:

Evidence for use

Cannabis has a long history of medicinal use in several cultures, however, there is very limited data from which to draw specific recommendations.

The National Drug and Alcohol Research Centre (NDARC) has reviewed available evidence for use in certain conditions, and developed guidance documents (note these are not clinical guidelines, nor are they endorsed by the NHMRC):

- [Guidance for the Use of Medicinal Cannabis in Australia: Overview.](#)
 - [Multiple Sclerosis](#)
 - [Palliative Care](#)

- [Epilepsy in Paediatrics and Young Adults](#)
- [Nausea and Vomiting](#)
- [Chronic Non-cancer Pain](#)

- These provide background, describe various forms of administration in specific settings, and reference efficacy and side-effects.

Medicinal cannabis pharmacology

- Most pharmacokinetic and pharmacodynamic data is related to Tetrahydrocannabinol (THC).
- Cannabidiol (CBD) data is being developed.
- Some patients may have trialled self-sourced cannabis products. This should be discouraged due to increased rates of adverse effects, side-effects, and variable absorption and concentration of active ingredients.

Products

There are currently no locally produced legal medicinal cannabis products available in Australia.

Application to prescribe must be for lawfully manufactured or imported products. The application must include full details of the product including its form, composition, administration, and dosage.

Some cannabis-based products have been formally assessed for quality, safety, and efficacy by a medicines regulator in Australia or another country, including:

- [Nabiximols \(Sativex\)](#) for managing spasticity associated with multiple sclerosis
- [Dronabinol](#) for anorexia in AIDS patients and chemotherapy-induced nausea and vomiting
- [Nabilone](#) for chemotherapy-induced nausea and vomiting.

Applications to prescribe are not limited to these products, however the product applied for must be legally produced and manufactured to appropriate quality standards with evidence supporting use of the particular product for the relevant patient.

Dosing

- The general principle is to "start low and go slow".
- Cannabis-naive patients may only need 0.1 to 0.5 of the starting dose of regular users.
- Review pharmacokinetics of the product before prescribing.
- Cease if:
 - desired effect not apparent in 4 to 12 weeks.
 - psychoactive.
 - other side-effects are prohibitive.

Route of administration

- Routes of administration vary. Most oils available are best absorbed sublingually
- Sublingual administration
 - Slowly absorbed, with effects delayed for 30 to 90 minutes.
 - Peak effects 2 to 4 hours after dose. Effects last 8 to 14 hours.
 - Best for symptoms where control is needed over a longer time frame.
 - Bioavailability 10 to 20%.

Adverse events, interactions and contradictions

Adverse events details with most cannabinoids are lacking, but include:

- Sedation
- Convulsions
- Gastrointestinal effects
- Cognitive effects e.g., anxiety, dysphoria, euphoria, hallucinations, paranoia, acute memory impairment, and reduced cognitive performance.

Drug interactions:

- THC and CBD are fat-soluble and require metabolism before excretion in faeces and urine. It may take 5 days to excrete 80 to 90% of the dose.
- Significant interactions are anticipated with [drugs metabolised by cytochrome P450](#), either inhibiting or inducing cytochrome P450 enzymes.

Contraindications:

- It is recommended against use in patients:
 - with previous psychotic or concurrent active mood or anxiety disorder.
 - who are pregnant, planning pregnancy, or breastfeeding.
 - with unstable cardiovascular disease

Warnings:

- Patients should not drive while treated with medicinal cannabis. Acute cannabis use is associated with increased motor vehicle accidents.
- Measurable concentrations of THC can be detected in saliva for many hours after administration.

2. Complete a **Comprehensive Clinical Assessment**

Comprehensive clinical assessment

- Presenting symptoms and underlying diagnosis
- Symptoms or disease that the medicinal cannabis is being considered
- Past medical history, especially cardiovascular, liver, and renal disease
- Medication review, including previously trialed medications
- Mental health history, especially mood disorders and schizophrenia
- Family history, including mood disorders and schizophrenia
- At-risk behaviours associated with drug of dependence or substance use disorder
- Social history including family responsibility, child safety, driving, and falls risk

3. Consider consulting a colleague and seeking **specialist input**

Seeking specialist input

- The prescriber should have an ongoing therapeutic relationship with the patient and manage coordination of care to ensure other prescribers are not prescribing cannabis, opioids, or opioid substitution therapy for the patient
- Best clinical practice involves including input by the patient's specialist, who:
 - should be treating the disease or symptom complex for which the cannabis product is prescribed.
 - has an ongoing therapeutic relationship with the patient.
 - may be aware of appropriate clinical trials.
- Always involve a paediatrician if treating a child.

Management

1. Develop a **treatment plan**

Treatment plan

- *The initial plan should cover 1 to 3 months of treatment and be reassessed.*
- *The plan should include:*
 - *clear goals of treatment and how this will be measured e.g., reduction in symptoms being treated, weight gain, improved function, objective measures of pain*
 - *documented specialist support*
 - *coordination of care with other treating doctors*
 - *the product, dose, and access to the product*
 - *risk management e.g., weekly dispensing if there are dose escalation concerns*
 - *monitoring arrangements e.g., timing of reviews*
 - *a strategy for ceasing if goals are not met*
 - *informed consent of the patient including experimental nature of use of unregistered medicines, product information (approved product information is only available for registered medicines), and agreement with the plan, including discontinuation if goals are not reached.*

2. Consider

- access to adult **clinical trials**

Clinical trials

- *Adult palliative care patients – focuses on quality of life, particularly appetite and appetite-related symptoms.*
- *Adults with chemotherapy-induced nausea and vomiting – where standard treatment is ineffective.*
- the **compassionate access scheme and clinical trials**, for children with severe treatment-resistant refractory epilepsy.

Compassionate access scheme for epileptic children

The Victorian Government has funding to provide access for up to 60 children with severe intractable epilepsy until June 2020.

For more information, contact the [Office of Medicinal Cannabis](#).

3. Review prescribing requirements:

- Depending on the product, both [Commonwealth TGA](#) and [Victorian State DHHS](#) approval is required.
- Medical practitioners can now apply for both TGA Special Access Scheme approval and a Victorian Schedule 8 (S8) treatment permit using the [TGA's single online application](#).

4. Prescribe under **Victorian regulations**.

Victorian Regulations

All prescriptions must comply with Victorian [Schedule 8 notifications](#) and [S8 permit](#) requirements.

No Commonwealth approvals are required in order to prescribe medicinal cannabis products registered on the [Australian Register of Therapeutic Goods \(ARTG\)](#).

[Nabiximols](#) (Sativex) is the only S8 medicinal cannabis product approved for use in Australia and registered on the ARTG:

- Can be prescribed with an [S8 Treatment permit](#).
- Only approved indication is: treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

Apply to access other unapproved imported medicinal cannabis products via the [Special Access Scheme \(SAS\)](#).

5. Prescribe under **Commonwealth regulations** as required.

Commonwealth regulations

- The TGA administer the Therapeutics Goods Act which provides the mechanism to access medicinal cannabis.
- Because medicinal cannabis products are not yet registered with the [Australian Register of Therapeutic Goods \(ARTG\)](#), a special application (or in limited cases, notification) is necessary.
- This can be made concurrently with a Victorian application.
- There are several pathways available to access unapproved therapeutic goods, including:
 - [the Special Access Scheme \(SAS\)](#) and
 - [Authorised Prescriber \(AP\) Scheme](#).

See [Online Guidance Tool](#) to help determine the appropriate access pathway to be used in any given circumstance.

- To prescribe for an individual patient, use the **Special Access Scheme (SAS)**.

Special Access Scheme (SAS)

The [Special Access Scheme \(SAS\)](#) provides for the import and/or supply of unregistered therapeutic goods (i.e., medicinal cannabis) for a single patient.

SAS contact details:

- Email: SAS@health.gov.au
- Phone: **1800-020-653 or (02) 6232-8644**
- Fax: **(02) 6232-8112**
- Postal address: The Medical Officer (SAS), Pharmacovigilance and Special Access Branch, Therapeutic Goods Administration, PO Box 100, Woden, ACT 2606, Australia
- [Website](#)

If the patient is terminally ill and likely to die within a matter of months, apply under **SAS Category A**.

SAS Category A

- This is a notification pathway for terminally ill patients where death is likely to occur within a matter of months. No application is required.

- Products currently available from wholesalers within Australia are not available for supply through SAS category A.
- Medical practitioners may supply a category A product to an eligible patient without the approval of the TGA, but must notify the TGA within 28 days.
- To notify the TGA:
 - Complete the [SAS Category A Notification Form](#).
 - Fax to **(02) 6232-8112**.
- Notifications are not acknowledged by the TGA.
- State and Territory legislation and import requirements from the Office of Drug Control still apply.
- For more information, see TGA – [Special Access Scheme](#).

For all other individual patients, apply under **SAS Category B**.

SAS Category B

- This is an application pathway for patients who do not meet the Category A criteria (end-stage terminal illness) – approval is required before a product can be prescribed.
- To apply:
 - Complete the [SAS Category B Application Form](#), including supporting evidence and product details.
 - Fax to **(02) 6232-8112**.
- The time frame for responses is 2 to 3 working days.
- Approvals are valid for a period up to 12 months from the approval date.
- For more information, see TGA – [Special Access Scheme](#).

To prescribe to multiple patients or types of patients, apply to become an **Authorised Prescriber (AP)**.

Authorised Prescriber (AP)

The [Authorised Prescriber Scheme](#) enables authorised medical practitioners to prescribe a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of patients) with a particular medical condition.

To apply:

- Prepare an application, including:
 - [Authorised Prescriber Scheme Application Form](#),
 - [Agreement to Treatment Directions Form](#),
 - treatment protocol (include supporting evidence, product details), and
 - [endorsement from a human research ethics committee or specialist college](#).
- Send via:
 - Email: eps@health.gov.au (preferred)
 - Fax: **(02) 6232-8112**

Time frame for response is a maximum of 10 working days, dependent on applications containing all necessary information.

6. The process for supply of medicinal cannabis varies according to the scheme prescribing under and whether the product is available within Australia.
 - **Obtaining products available in Australia** (patients with SAS B approval or AP authority only)

Obtaining products in Australia

- The Office of Drug Control maintains a list of [licensed manufacturers and/or suppliers of medicinal cannabis products](#).
- Contact the chosen manufacturer or supplier and provide them with:
 - either the SAS-B approval or AP authorisation, and
 - state approval.

Obtaining products requiring import (patients with SAS A notification, SAS B approval, or AP authority)

Obtaining products requiring import

The prescriber or pharmacist must either:

- obtain a [licence](#) and a [permit to import](#) the unregistered product, issued under the Customs (Prohibited Imports) Regulation by the [Commonwealth Office of Drug Control \(ODC\)](#) for each shipment.
 - Import permits are issued on a case-by-case basis.
 - SAS-A applications are given priority and should be assessed within 1 working day.
 - SAS-B and AP applications will be processed within a maximum of 30 working days.
- obtain the product from an importer holding both:
 - a licence from the Victorian Department of Health and Human Services to supply the product by wholesale, and
 - a licence and a permit to import the product issued by the ODC.
- obtain the product from a manufacturer licensed by the TGA, the ODC, and the Victorian Department of Health and Human Services (or the equivalent authority in its home Australian state or territory) to manufacture the product.

In all instances, the prescriber must provide the supplier with either the SAS-A notification, SAS-B approval, or AP authority form.

Referral

In Victoria, **any medical practitioner** can prescribe a medicinal cannabis product for their patient, if they have a S8 treatment permit and TGA approval, and believe it is clinically appropriate to do so.

Any medical practitioner

For privacy reasons, the TGA does not publish a list of Authorised Prescribers who have been authorised to supply medicinal cannabis products under the Therapeutic Goods Act 1989.

Furthermore, in Australia doctors are not allowed to advertise to the public that they are able to prescribe a particular medicine. This is not just a matter relating to the Therapeutic Goods legislation, but also to the standards upheld by the Australian Health Practitioner Regulation Agency and the Medical Board of Australia and goes to matters of medical ethics and good medical practice.

If you do not wish to prescribe or require advice, seek input from:

- a specialist involved in the patient's care.

- a specialist experienced in medicinal cannabis.
- the [*Victorian Cannabis Medicines Advisory Service*](#) on **(03) 9096-7768** or email medicinal.cannabis@dhhs.vic.gov.au.

Information

For health professionals

- Alcohol and Drug Foundation – [Medicinal Cannabis](#)
- Australian Prescriber – [Medicinal Cannabis](#)
- [Centre for Medicinal Cannabis Research and Innovation](#)
- Health.Vic – [Access to Medicinal Cannabis in Victoria: Information for Medical Professionals](#)
- Therapeutic Good Administration (TGA):
 - [Access to Medicinal Cannabis Products](#)
 - [Guidance for the Use of Medicinal Cannabis in Australia: Overview](#)

For patients

- Health.Vic – [Access to Medicinal Cannabis in Victoria: Information for Patients and Carers](#)
- Therapeutic Goods Administration (TGA) – [Guidance for Use of Medicinal Cannabis in Australia: Patient Information](#)

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