

## Frequently asked questions

# Medicinal cannabis

### What is cannabis?

The term cannabis is widely used to refer to any plant in the genus Cannabis including dried flowers and leaves (marijuana), seeds, extracts and resins. Between 60 and 100 chemicals called cannabinoids and some 300 non-cannabinoid chemicals are produced by the cannabis plant.

Delta-9 tetrahydrocannabinol (THC) is the main cannabinoid responsible for the 'high' and psychoactive effects produced by cannabis, and the reason for recreational use as an illicit drug.

### What is medicinal cannabis?

The main cannabinoids studied and currently thought to be the most important for medical use are delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD). Many other cannabinoids exist and a number are being researched for possible medical use.

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

Crude cannabis is difficult for doctors to prescribe because the specific components (chemicals known as cannabinoids), the dose and potency in each plant is not known or standardised.

Pharmaceutical preparations of cannabis contain specific active components in known amounts and mixtures, which optimise the therapeutic benefit and minimise side effects. The dose and strength of the preparation can be controlled and standardised, making it safer for patients to use.

The Commonwealth Department of Health regulates medicinal cannabis products through the [Therapeutic Goods Administration \(TGA\)](#) and the [Office of Drug Control \(ODC\)](#).

### What are the benefits of medicinal cannabis?

There is little high quality research on the benefits of medicinal cannabis and the clinical evidence for its role is still under discussion and being investigated through clinical trials.

Medicinal cannabis preparations have been used with some reported success to relieve symptoms in some specific conditions, such as reducing spasticity and muscle pain in people with multiple sclerosis.

There is also some evidence that medicinal cannabis may be useful in treating seizures, nausea and vomiting due to chemotherapy, and also as an appetite stimulant for people living with human immunodeficiency virus (HIV) infection or cancer.

The Commonwealth TGA has published guidance materials for doctors to support them in determining whether prescribing medicinal cannabis is appropriate and beneficial. Refer to the [TGA](#) for information.

### What are the side effects of medicinal cannabis?

It is important that medicinal cannabis is only used under medical supervision because it may interact with other medicines a patient is taking or cause adverse reactions.

The known acute side-effects from medicinal cannabis treatment (both CBD and THC) include fatigue and sedation, vertigo (dizziness), nausea and vomiting, fever, decreased or increased appetite, dry mouth, and diarrhoea.

THC (and products high in THC) have been associated with feeling high or feeling dissatisfied, depression, confusion, hallucinations, paranoid delusions, psychosis, and cognitive distortion

(having thoughts that are not true).

### **What is the current legal status of medicinal cannabis?**

Amendments to the *Narcotics Drugs Act 1967* to allow the controlled cultivation of cannabis for medicinal or scientific purposes under a national licensing scheme came into operation on 30 October 2016. The Commonwealth Government is responsible for issuing licences and permits under this scheme.

These amendments do not legalise the growing or use of cannabis for non-medical purposes nor do they legalise the cultivation of cannabis or its use outside of regulated medicinal purposes. They also do not make cannabis products available over the counter without a prescription from an authorised specialist medical practitioner.

Commonwealth [scheduling changes](#) to medicinal cannabis in effect from 1 November 2016, mean certain cannabis products are Schedule 8 medicines (controlled drugs) when used for medicinal purposes, in accordance with the *Narcotics Drugs Act 1967* and the *Therapeutic Goods Act 1989*. These medicinal cannabis products are prescription only medicines in the same schedule as medicines such as morphine and oxycodone.

South Australia adopts the Commonwealth scheduling and from 1 November 2016, medical practitioners in South Australia can legally prescribe medicinal cannabis products with Commonwealth approval and relevant State approval for purposes of South Australian Controlled Substances legislation.

The State Government released a [patient access pathway](#) in April 2017 to clarify access in South Australia.

Medicinal cannabis is lawful when the cultivation, manufacture, prescribing, and supply complies with all applicable Commonwealth and State laws. All other types of cannabis remain prohibited.

### **What about cannabidiol?**

One cannabis derivative, cannabidiol (*in preparations for therapeutic use where cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation*) is considered a Schedule 4 drug; the preparation must comply with the [Poisons Standard](#). Cannabidiol products are currently unapproved (unregistered) therapeutic goods in Australia and require Commonwealth approval or notification to prescribe (e.g. approval under Special Access Scheme B via the TGA SAS online system).

An authority for purposes of South Australian Controlled Substances legislation is not required to prescribe a Schedule 4 cannabidiol drug.

### **Does legislation that deals with medicinal cannabis mean that it is now legal to smoke cannabis?**

No, cannabis remains a highly regulated drug in Australia and its use and supply is controlled by a number of Commonwealth, State and Territory laws. Patients will not be able to access medicinal cannabis products for smoking.

### **Do the legislative changes mean I can now grow my own medicinal cannabis legally?**

No, people cannot legally grow their own cannabis for medicinal use; even it has been prescribed for them by an authorised medical practitioner.

Throughout Australia, it remains illegal to cultivate cannabis or manufacture cannabis products. The only exception will be where cultivation and manufacture is done under a licence and a permit granted under the Commonwealth licensing scheme for medicinal use.

## Who can prescribe an unregistered medicinal cannabis product?

Supply of unapproved (unregistered) therapeutic goods such as medicinal cannabis requires TGA approval/notification and is reserved for exceptional clinical circumstances including circumstances where other established treatments have failed.

Prescribing of unapproved therapeutic goods is generally restricted to medical practitioners with expertise in the management of the specific condition being treated. If the medical practitioner is not a specialist in the condition and is submitting an application, then depending on the circumstances, a report from the appropriate treating specialist on the use and suitability of the product in the particular condition may be required.

## What approvals or notifications are required to prescribe unapproved/unregistered medicinal cannabis products?

To prescribe or supply an unapproved (unregistered) medicinal cannabis product requires Commonwealth approval or notification under the applicable Commonwealth schemes. These are the [TGA Special Access Scheme, Authorised Prescriber Scheme or Clinical Trials Schemes](#). To apply to prescribe an unregistered medicinal cannabis product under the TGA Special Access Scheme go to <https://www.tga.gov.au/special-access-scheme-online-system>.

Approval under South Australian Controlled Substances legislation is also required to prescribe a Schedule 8 medicinal cannabis product where it is being prescribed for longer than two months, or to patient already prescribed a Schedule 8 drug for a period exceeding two months, and for any person the medical practitioner reasonably believes to be dependent on drugs.

Exemptions apply in South Australia for patients aged over 70 years of age, and terminally ill patients whose doctors have notified the Drugs of Dependence Unit (Notified Palliative Care Patients).

For more information about requirements under South Australian Controlled Substances legislation, health practitioners can contact the Drugs of Dependence Unit on 1300 652 584.

## How will patients obtain medicinal cannabis products?

Medicinal cannabis products for therapeutic use that meet Therapeutic Goods Administration (TGA) standards can be supplied on prescription in South Australia when prescribed by a medical practitioner with the required approvals or notifications, and dispensed by a pharmacist

Medicinal cannabis products are not available over the counter and patients will not be able to access medicinal cannabis products for smoking or for recreational use.

## What is the Government of South Australia doing?

The South Australian Government is committed to ensuring South Australian consumers have access to the optimal range of safe and effective treatments and services to promote the best health outcomes for patients and the community. South Australia adopts the Commonwealth scheduling and since 1 November 2016, medical practitioners can legally prescribe medicinal cannabis products with the required Commonwealth and State approvals.

Following consultation, the State Government released a patient access pathway in April 2017 to clarify access for South Australians. The Government of South Australia does not have a role in issuing licences or permits for the cultivation of medicinal cannabis.

From October 2018 South Australian medical practitioners have access to a single online application system for unregistered medicinal cannabis products through the TGA Special Access Scheme (SAS) online system. Medical practitioners can apply to prescribe a medicinal cannabis product through a single online application process to fulfil both Commonwealth and South Australian Controlled Substances legislative requirements.

Use of the TGA SAS online system reduces administrative burden on health practitioners and ensures faster access for patients to medicinal cannabis products. To access the TGA SAS online system, go to <https://sas.tga.gov.au>.

### **Will medicinal cannabis products be subsidised under the Commonwealth Government's Pharmaceutical Benefits Scheme?**

Medicinal cannabis products are not currently subsidised under the Pharmaceutical Benefits Scheme (PBS). Medicines must be registered products, listed on the Australian Register of Therapeutic Goods (ARTG) before they can be considered for PBS subsidy.

### **Where can I find more information about access to medicinal cannabis?**

For more information about the Commonwealth licensing scheme for licences and permits, visit the Office of Drug Control website at [www.odc.gov.au/medicinal-cannabis](http://www.odc.gov.au/medicinal-cannabis). For more information about access to medicinal cannabis products and Commonwealth approval necessary to prescribe unregistered medicinal cannabis products, visit the Therapeutic Goods Administration website at [tga.gov.au](http://tga.gov.au).

To apply for an authority to prescribe medicinal cannabis in South Australia, medical practitioners can apply via the [TGA Special Access Scheme Online system](#).

For detailed information about requirements to prescribe medicinal cannabis products under the South Australian Controlled Substances legislation go to [www.sahealth.sa.gov.au/medicinalcannabis](http://www.sahealth.sa.gov.au/medicinalcannabis) or contact the [Drugs of Dependence Unit](#) on telephone 1300 652 584.

### **Is there a list of doctors who can prescribe medicinal cannabis?**

Australia doctors are not allowed to advertise to the public that they are able to prescribe a particular medicine. This is related to the Therapeutic Goods legislation, and 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. Furthermore, for privacy reasons we do not publish or provide the names of doctors who prescribe medicinal cannabis products.

### **Can I drive while being treated with medicinal cannabis?**

Patients should not drive or operate machinery while being treated with medicinal cannabis. In addition measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine many days after the last dose. It may take up to five days for 80 to 90 per cent of the dose to be excreted. Drug-driving is a criminal offence, and patients should discuss the implications for safe and legal driving with their doctor.

### **Can I import a product over the internet or by post?**

Personal import of medicinal cannabis products is not permitted other than through the traveller's exemption process. Please refer to the [TGA](#) for information.

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## For more information

**Medicines and Technology Programs  
Department for Health and Wellbeing  
SA Health**  
[www.sahealth.sa.gov.au/medicinalcannabis](http://www.sahealth.sa.gov.au/medicinalcannabis)



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