

Fact Sheet

Approvals to prescribe medicinal cannabis in SA

Cannabis for human therapeutic use is regulated as a medicine in Australia. Medical practitioners can legally prescribe medicinal cannabis products that are unapproved therapeutic goods, subject to both Commonwealth and State regulatory requirements.

Commonwealth schemes to supply an unapproved therapeutic good

The Therapeutic Goods Administration (TGA) provides access for medicinal cannabis products that are not approved for use in Australia under the following schemes:

- > [Special Access Schemes](#)
- > [Authorised Prescriber Scheme](#)
- > [Clinical Trial Schemes](#)

Currently there is only one approved medicinal cannabis product listed on the Australian Register of Therapeutic Goods; Sativex® (nabiximols).

Sativex is a Schedule 8 drug approved for use as add-on treatment of moderate to severe MS spasticity (refer to the approved Product Information for details). Sativex is already approved by the TGA for use in Australia; usual approval processes applicable to Schedule 8 drugs in South Australia apply to Sativex (see below).

All other medicinal cannabis products, including cannabidiol (CBD) products, are unapproved (unregistered) therapeutic goods and require approval to prescribe from the TGA. Approval to prescribe an unapproved medicinal cannabis product is most commonly through the TGA Special Access Scheme (SAS) Category B.

Applying to prescribe an unapproved medicinal cannabis product under the TGA Special Access Scheme (SAS)

Medical practitioners can apply to prescribe an unapproved 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>.

The [TGA SAS online system](#) for applications to prescribe an unregistered medicinal cannabis product combines both SA Health and TGA requirements in one online application.

Requirements under South Australian law to prescribe Schedule 8 medicinal cannabis products

The [South Australian Controlled Substances Act 1984](#) regulates the prescribing and supply of medicines in South Australia and applies to medicinal cannabis products.

A section 18A authority to prescribe a medicinal cannabis product that is a Schedule 8 controlled drug (drug of dependence) is required:

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- after two months of treatment, or
- before commencing treatment where the person has been prescribed another Schedule 8 drug for a period exceeding two months, or
- before commencing treatment for any person the medical practitioner reasonably believes to be dependent on drugs.

Exemptions - A section 18A authority is not required for patients:

- > aged 70 years or older
- > Notified Palliative Care Patients (notification must be made to the Drugs of Dependence Unit).

For information about section 18A authority requirements relevant to patients receiving treatment in a hospital or correctional institution, health practitioners should contact the SA Health Drugs of Dependence Unit.

Medicinal Cannabis Products

Before applying the medical practitioner should identify a medicinal cannabis product appropriate for the patient and clinical condition. Information about the products accessible in Australia and contact details for approved suppliers of these products is available on the Commonwealth Office of Drug Control website at www.odc.gov.au. Health practitioners can contact approved suppliers for information about the products they have available for supply on prescription in Australia.

Cannabidiol (CBD)

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.

For more information about requirements under South Australian Controlled Substances legislation, health practitioners can contact the Drugs of Dependence Unit:

Web: sahealth.sa.gov.au/drugsofdependence

Email: HealthDrugsofDependenceUnit@sa.gov.au

Phone: 1300 652 584

For more information about TGA requirements to prescribe an unapproved therapeutic good, or submitting an application via the TGA SAS online system, contact the TGA:

Web: www.sas.tga.gov.au

Email: info@tga.gov.au

Phone: 1800 020 653

For more information

**Medicines and Technology Programs
Department of Health and Wellbeing
SA Health**

www.sahealth.sa.gov.au/medicinalcannabis

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