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Medicinal Cannabis

# Medicinal Cannabis

The ACT Medicinal Cannabis Scheme aims to provide patients with safe and legal access to high quality medicinal cannabis products in appropriate circumstances.

The term medicinal cannabis refers to cannabis that is intended for therapeutic use and is regulated as a prescription pharmaceutical formulation. This differs from raw botanical cannabis that is consumed or smoked for recreational or medical purposes.

Certain medicinal cannabis formulations may be legally prescribed in the ACT.

Most medicinal cannabis formulations in Australia are unapproved therapeutic goods, which means they have not been assessed by the Therapeutic Goods Administration (TGA) for safety, quality or effectiveness and are not included on the Australian Register of Therapeutic Goods (ARTG). Prescribers wishing to access unapproved medicinal cannabis products for their patients may apply to the TGA through the Special Access Scheme (SAS) or Authorised Prescriber Scheme.

Some medicinal cannabis products are included on the ARTG and therefore approved by the TGA for use in Australia, for example nabiximols (Sativex®).

Medicinal cannabis products may be available as either schedule 8 (controlled), schedule 4 (prescription only) and schedule 3 (pharmacist only) medicines, depending on the type and concentration of active ingredient(s) they contain.

All other forms of cannabis cannot be prescribed for medicinal use.

Please contact the Pharmaceutical Services section of the ACT Health Protection Service on [02 5124 9208](tel:0251249208) (tel:+61251249208) for questions about medicinal cannabis.

## Medicinal Cannabis Prescriber Approvals

There are many forms of medicinal cannabis available. In the ACT, prescribers must have approval from the ACT Chief Health Officer and from the TGA to prescribe unapproved schedule 8 (controlled medicine) medicinal cannabis products.

ACT Chief Health Officer approval is not required to prescribe schedule 4 (prescription only) or schedule 3 (pharmacist only) products however TGA approval may still be required.

ACT prescribers may apply for both TGA and ACT Chief Health Officer approvals concurrently through the TGA's single online application form. This consolidated form has been developed to streamline the application process for prescribers and facilitate more timely patient access to medicinal cannabis products.

The TGA and ACT Health will each conduct their own evaluation based on the information submitted via the online application system and may seek additional information from the prescriber, if required.

The TGA will evaluate the application under the requirements of the *Therapeutic Goods Act 1989* (<https://www.legislation.gov.au/Series/C2004A03952>) and ACT Health will evaluate the application against the requirements of the ACT Controlled Medicines Prescribing Standards (<https://www.legislation.act.gov.au/ni/2021-161/>). Both the TGA and ACT Health must approve the application prior to a prescriber being permitted to prescribe medicinal cannabis.

**The TGA offers two different approval options, as outlined below, with differing supply processes:**

**1. Special Access Scheme (SAS) approvals**

SAS approvals are only for individual patients, whereby prescribers are authorised to write a prescription for a patient who obtains supply from a community pharmacy.

This approval process is the preferred option, as identified by the TGA website.

Prescribers seeking SAS approval are able to apply for ACT Chief Health Officer approval concurrently via the TGA's single online application form.

**2. Authorised Prescriber Scheme (AP) approvals**

The AP scheme allows prescribers to obtain an approval from the TGA for a group of patients with a particular indication, instead of obtaining individual SAS approvals. This scheme authorises the approved prescriber to supply an approved product directly to a patient during a consultation.

Under this scheme, ACT prescribers will also be required to:

- Separately seek ACT Chief Health Officer approval for each patient;
- Arrange supply of the product to the practice directly from the sponsor or a pharmacy;
- Ensure appropriate storage of schedule 8 (controlled) medicines;
- Ensure supply is provided in accordance with the ACT Medicines, Poisons and Therapeutic Goods Regulation 2008 (<https://www.legislation.act.gov.au/sl/2008-42/>), including labelling and reporting requirements.

For additional information on the Authorised Prescriber or Special Access Scheme, or to apply for TGA approval to prescribe medicinal cannabis, please visit the TGA website (<https://www.tga.gov.au/medicinal-cannabis-information-health-professionals>).

From 26 January 2021, ACT Health no longer requires submission of supporting clinical documentation with any medicinal cannabis application for non-drug dependent patients.

Nurse Practitioners are currently unable to access the TGA online application portal and are required to contact the TGA directly for further information. The TGA is working on correcting this issue in 2021. To obtain ACT Chief Health Officer approval nurse practitioners should complete the standard application form for Approval to Prescribe Controlled Medicines (<https://www.health.act.gov.au/sites/default/files/2023->

[01/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf](https://www.health.act.gov.au/sites/default/files/2023-01/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf)

until the portal access is available.

Interstate prescribers who hold a current TGA approval to prescribe medicinal cannabis for a patient requiring dispensing from an ACT pharmacy are required to obtain an ACT Chief Health Officer approval. Prescribers are advised to complete the [Approval to Prescribe Controlled Medicines application form](https://www.health.act.gov.au/sites/default/files/2023-01/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf) (<https://www.health.act.gov.au/sites/default/files/2023-01/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf>) and submit to ACT Health together with a copy of the TGA approval.

Prescribers wishing to prescribe a product approved for use in Australia (for example; nabiximols (Sativex®)) should apply to the ACT Chief Health Officer to prescribe a controlled medicine using the [Approval to Prescribe Controlled Medicines application form](https://www.health.act.gov.au/sites/default/files/2023-01/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf) (<https://www.health.act.gov.au/sites/default/files/2023-01/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf>). TGA SAS or AP approval is not required.

## Supply of Medicinal Cannabis

Pharmacists are authorised to supply medicinal cannabis on a valid prescription or purchase order from a prescriber and may require TGA approval documentation to order from a supplier.

Pharmacists may need to apply to the TGA and the Office of Drug Control to seek approval to obtain medicinal cannabis.

Some medicinal cannabis products require refrigeration, which poses issues with safe storage.

Please contact the Health Protection Service on [\(02\) 5124 9208](tel:(02)51249208) (tel:+61251249208) to discuss arrangements for safe storage if a patient wishes to access a refrigerated product.

## Further information

Please see the links below for more information:

- [Medicinal Cannabis - for practitioners factsheet](https://www.health.act.gov.au/sites/default/files/2021-04/Medicinal%20Cannabis%20Scheme%20-%20Prescribers%20and%20pharmacists.pdf) (<https://www.health.act.gov.au/sites/default/files/2021-04/Medicinal%20Cannabis%20Scheme%20-%20Prescribers%20and%20pharmacists.pdf>)
- [Medicinal Cannabis - Patient Information](https://www.health.act.gov.au/sites/default/files/2021-04/Medicinal%20Cannabis%20-%20Patient%20Information.pdf) (<https://www.health.act.gov.au/sites/default/files/2021-04/Medicinal%20Cannabis%20-%20Patient%20Information.pdf>)
- [Single online ACT-TGA Medicinal Cannabis application](https://sas.tga.gov.au/) (<https://sas.tga.gov.au/>)
- [Office of Drug Control website](https://www.odc.gov.au/) (<https://www.odc.gov.au/>)

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