NPS MEDICINEWISE

Australian Government
Department of Health

Accessing 'unapproved' medicinal cannabis products

Authorised Prescriber (AP) and Special Access Scheme (SAS) applications for 'unapproved'[1] medicinal cannabis products are made by active ingredient, under one of five categories based on cannabinoid content.

Table 1: The five active ingredient categories for 'unapproved' medicinal cannabis products

Category	Category description
Category 1*	CBD medicinal cannabis product (CBD ≥ 98%)
Category 2#	CBD-dominant medicinal cannabis product (CBD ≥ 60% and < 98%)
Category 3#	Balanced medicinal cannabis product (CBD < 60% and ≥ 40%)
Category 4#	THC-dominant medicinal cannabis product (THC/other non-CBD cannabinoids 60–98%)
Category 5#	THC medicinal cannabis product (THC/other non-CBD cannabinoids > 98%)

CBD = cannabidiol; THC = tetrahydrocannabinol; * = Schedule 4; # = Schedule 8

Products in Categories 1–3 are included in the Therapeutic Goods Administration's (TGA)'s **List of medicinal cannabis medicines with established history of use** for certain conditions (chronic pain and anxiety) and dosage forms (oral liquid and capsule).

The TGA strongly encourages consumers and health professionals to report any suspected adverse events involving medicinal cannabis products.
This helps build a profile on the safety of an 'unapproved' product.

Resources for prescribers

- Australian Prescriber: **Prescribing medicinal cannabis**
- TGA: **Accessing medicinal cannabis for a patient**
- TGA: **Authorised Prescribers**
- TGA: **Special Access Scheme**
- TGA: **Guidance for the use of medicinal cannabis in Australia - Overview**
- NPS MedicineWise: **Active ingredient prescribing and primary care**

Resources for pharmacists

- NPS MedicineWise: **Medicinal cannabis: process for dispensing**
- NPS MedicineWise: **Medicinal cannabis: seven questions pharmacists are asking**
- NPS MedicineWise: **Active ingredient prescribing: supporting knowledge and choice**

Consultation with the patient

Decision to prescribe an 'unapproved' medicinal cannabis product after considering appropriate treatment options on the ARTG for the condition.

Select a clinically suitable medicine

Prescribers may wish to refer to the TGA's **Published list of medicinal cannabis products** stratified by the five active ingredient categories.

Is the medicine's active ingredient category and dosage form included in the TGA's List of medicinal cannabis medicines with established history of use?

Medicines on this list are generally:

- Category 1–3, and
- either an oral liquid or capsule, and
- intended for the treatment of refractory chronic pain or refractory anxiety in adults.

YES

Authorised Prescriber (AP) Scheme

- Any **Australian registered medical practitioner** can become an AP by applying through the **SAS & AP Online System** (there is no charge for applying).
- APs can prescribe medicinal cannabis directly to their patients, without requiring clinical justification or separate approval for individual patients.
- The TGA does not need to be notified each time medicinal cannabis products are prescribed during the approval period (up to 5 years).
- APs must report to the TGA the number of patients they treat every 6 months.

NO

Human Research Ethics Committee approval or specialist college endorsement for access via AP Scheme is required if selected medicine is:

- Category 4–5, and/or
- dosage forms not an oral liquid or capsule, and/or
- intended for the treatment of a condition other than refractory chronic pain or refractory anxiety in adults.

Special Access Scheme (SAS)

- Allows prescribers (including nurse practitioners) to prescribe medicinal cannabis for a single patient on a case-by-case basis.
- Complete the **SAS Category B** application using the **SAS & AP Online System** (typically 2–3 working days).
- Include clinical justification for the use of the product. The TGA may request supporting evidence for some novel indications or evidence of specialist support from a practitioner with appropriate expertise.

TGA Approval

Following approval, prescriptions may be written for medicines within that category of medicinal cannabis product.

Write a prescription

Include the active ingredient name(s) on the prescription. Prescribers may wish to specify the brand name where clinically necessary.

Pharmacy

Pharmacists should dispense the medicine in accordance with their relevant state or territory drugs and poisons legislation.

Pharmacists should clarify or request a new prescription if it doesn't contain enough information to identify a particular product.

[1] Unapproved medicines are products that are not registered on the Australian Register of Therapeutic Goods (ARTG). Most medicinal cannabis products are 'unapproved' therapeutic goods, which means they have not been assessed by the TGA for safety, quality or effectiveness. This excludes Sativex (nabiximols) and Epidyolex (cannabidiol) which are included in the ARTG for specific indications.

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Independent. Not-for-profit. Evidence-based. This program is funded by the Australian Government Department of Health.

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