

Patient Access to Medical Cannabis in Australia

In Australia, medical cannabis is currently generally classified as an unregistered product - unlike the registered prescription medicines that you are used to accessing through the PBS (Pharmaceutical Benefit Scheme). Despite this, patients can still access medical cannabis and this is a brief guide to how this process works from the patient's perspective.

Medical cannabis products can be accessed via the following three access pathways:

- Special Access Scheme (SAS) There are two pathways: 'A' and 'B'.
- Authorised Prescribers
- Clinical trials

Authorised prescribers deal with a specific group of patients with the same diagnosis. Any doctor can prescribe medicinal cannabis without becoming an 'authorised prescriber.' This method of access is often used by specialist doctors such as a doctor working exclusively with patients who have a diagnosis of HIV/AIDS or a specialist working in a neurology clinic who sees patients with multiple sclerosis. Clinical trials allow access but there are often specialised acceptance criteria and requirements that your doctor can guide you through if this pathway suits your needs.

If you have a diagnosis of a life-limiting illness your doctor may choose the streamlined 'SAS A' process but for most patients, Special Access Scheme (SAS) Category 'B' is the most common and quickest pathway a general practitioner can use to prescribe medical cannabis.

This document focuses on this common 'SAS B' pathway which facilitates access for a wide variety of patients with many different symptoms.

Special Access Scheme Category B (SAS B)

Medical Cannabis is not a first-line treatment. This means that, in most cases your doctor will need to try some other treatments for the symptoms that you have.

The government considers cannabinoid therapy something that should only be used after standard treatments have been unsuccessful or caused unacceptable side-effects or hold unacceptable risks.

As part of the application, your doctor will need to comment on the previous treatments that have been tried and what happened to justify the request for medicinal cannabis.

Step by Step Guide: using the ‘SAS B’ pathway to access Medicinal Cannabis

STEP 1: Doctor Consultation

As a first step you should see the doctor who knows you, or the symptom you are concerned about, best. For most patients, this will be your General Practitioner, but in some cases, it may be your specialist. If for example, you have an oncologist (cancer specialist) or respiratory physician (lung specialist) who you see regularly they may be willing to prescribe medical cannabis if the symptom of concern relates to the condition they are treating you for.

In Western Australia, a GP requires a letter from a specialist to support the prescribing of medical cannabis. In other states, this is needed only if the GP involved does not have sufficient expertise in the specific illness involved. This can occur particularly if your symptom is due to a rare condition that the GP may not encounter often.

The doctor that you see needs to be an Australian-registered medical practitioner with appropriate qualifications and/or expertise for the condition requiring treatment. The government has indicated that it favours the involvement of your usual GP in the prescribing of Medicinal Cannabis because that doctor knows you and your health, is aware of your history and has access to your medical record. This ensures that prescribing is both appropriate and safe and also makes sure that you can receive appropriate follow-up.

STEP 2: Product Consideration

If your medical practitioner decides that cannabinoid therapy is an appropriate treatment they will then need to determine exactly which product is suitable. They are likely to consider the following;

- Which 'mix' of cannabinoids is best to treat your symptom
- Which form of medical cannabis is best for your specific symptom
- Product availability
- The ongoing costs for you
- If it is a 'Schedule 4' medicine (Prescription Only) or 'Schedule 8' medicine (Controlled Drug) as the approval process and product delivery can differ

The doctor will also consider the safety and quality requirements that are dictated by the government. These requirements are set out in Therapeutic Goods Order No 93 (TGO93) and form an important part of the information that the medication supplier has to supply to the TGA (Therapeutic Goods Administration).

Remember that product choice is the responsibility of the doctor. You may have read a lot of information about Medical cannabis but it is a prescribed medication and your doctor needs to consider issues such as interactions with other medications you may be on, your liver function and your family history. They will research and compare products to find which best fits your symptoms and circumstances.

STEP 3: Application to TGA +/- State Health

Once the doctor has decided which medical cannabis product is appropriate they will ask you to consent to the application being made. The doctor then applies for approval using the 'SAS B' pathway.

The doctor needs to ensure that they can meet the TGA requirements. They need to ensure that:

- They have performed an appropriate history and examination
- They can submit documentation detailing medications that have been trialled for the condition but have been unsuccessful or have caused side-effects
- They have a treatment plan and a plan for your follow-up

CannaPacific is focussed on supporting GP's to effectively and safely prescribe medical cannabis for their patients. We have developed an online support portal that assists the

GP with the application process whilst ensuring that you and your GP remain in charge of all the decisions that affect your health and well-being.

STEP 4: Approval

The TGA will receive the application, and if everything is in order, issue an approval. Occasionally they may request more information from the doctor. Currently, if you live in NSW, Victoria, Queensland, WA, SA or the NT when the doctor receives an approval from the TGA they can proceed and issue the prescription.

For certain controlled Schedule 8 medicines, doctors in the ACT and Tasmania need to take a second step and apply to their State Health Department as well. Unfortunately, each Australian State and Territory has slightly different requirements for patients trying to access medical cannabis depending on which schedule listing the medical cannabis products fall under.

STEP 5: Patient Access

Once the doctor receives approval they can generate the prescription and approval for medical cannabis and you can then take these to your choice of pharmacy. Pharmacists do not usually keep medical cannabis on the shelves and it is important to remember that the script is item, manufacturer and patient-specific. The relevant Health Department approvals are sent to the wholesaler by the pharmacy. Wholesalers then release the specific prescribed product to the pharmacy who will finally dispense it to you.

Medical cannabis is a safe medication but it often requires a process of careful titration to be effective. It is important to return to see the prescribing doctor for follow-up and to ensure that you follow the prescribing directions carefully.