

Access to medicinal cannabis products in Australia

Resource for doctors

Step 1

Doctor has consultation with patient

Prescribing considerations

- Is a medicinal cannabis product appropriate for my patient?
- Do I have the appropriate expertise/qualifications? Should I consider specialist involvement?
- Review evidence for potential products in the context of the patient's condition.
- Use this information to guide specific product selection.

Depending on the circumstances, you may need to seek approval/authorisation from the TGA, your state/territory health department and/or the ODC before you can prescribe, access or arrange importation of medicinal cannabis products.

Seeking approval/authorisation for a specific medicinal cannabis product

- a) Gather product details – trade name, formulation, dosage form, route of administration, dose and product specifications.
- b) Follow steps 2A and 2B then:
 - 1) if imported stock is already in Australia or Australian manufactured stock is available, follow Step 3A.
 - 2) if stock must be imported into Australia, follow Step 3B. ***

For further information, see the TGA's Access to medicinal cannabis products webpage.

For assistance call 1800 220 007 (or 02 6232 8866) or email medicinal.cannabis@health.gov.au

Step 2A

TGA access schemes

For individual patients:

[Special Access Scheme Category A or B \(SAS A or SAS B\)](#)

Submit [notification/application](#) (for SAS B include supporting evidence, product details).

*Timeframe: 2-3 working days for SAS B**

For a class of patients:

[Authorised Prescriber \(AP\)](#)

Submit application – [Agreement to Treatment Directions form, treatment protocol](#) (include supporting evidence, product details), HREC/College endorsement.

*Timeframe: Max. 10 working days**

* Timing dependent on applications containing all necessary information.

Step 2B

Check your state/territory requirements

Rules relating to medicinal cannabis products may vary between states and territories.

[Contact your state/territory health department](#) to confirm requirements.

Obtain prescribing approval if required (may not be required if schedule 4, for example cannabidiol)

Timeframe: Dependent on state, but usually less than 20 working days



Import licence and permit (from the ODC)

*** If accessing through SAS A or intending to import product from overseas (Step 3B):

- Check import licence status of importer.
 - If no licence is held, importer must apply for a [licence from the ODC](#). (Max. 30 working days)
- Import permit is issued on a case by case basis.

Step 3A

If stock available in Australia

SAS B or AP only

Pharmacist or medical practitioner:

- Contact supplier.
- Provide supplier SAS B approval or AP authorisation and state/territory approval if required.
- Supplier releases product.

Step 3B

If product must be imported

Pharmacist or medical practitioner:

- Determine importer.
 - Importer must hold an [ODC licence](#). ***
- Send SAS A notification/SAS B approval/AP authorisation and state/territory approval to importer.

Importer:

- Apply to ODC for an import permit (per shipment).
*For SAS A notifications ODC give priority one working day assessment time**
- Liaise with overseas supplier.
- Exporter supplies product.
- Importation of product.
- Supply of product.

* Timing dependent on evidence of state/territory approval and quality of product.

PATIENT ACCESS