Medicinal cannabis:

Seven questions pharmacists are asking

1. Can I dispense medicinal cannabis prescriptions?

It may depend on your pharmacy type and state/territory legislation. Most states and territories currently allow community pharmacies to dispense medicinal cannabis provided they meet their specific state/territory health department requirements.

2. How do I prepare my pharmacy to be medicinal cannabis prescription ready?

To dispense unregistered medicinal cannabis prescriptions, you need to meet all legal requirements as stated by the Australian Government and relevant state/territory health departments.

Note that products containing 98% or more cannabidiol (CBD), and in which any other naturally occurring cannabinoids other than CBD eg, tetrahydrocannabinol (THC) comprise 2% or less of the total cannabinoid content, are Schedule 4 prescriptions. In general, products that contain THC are classified as Schedule 8.

Start by checking the requirements as specified by your relevant state/territory health department. Ensure you meet all criteria, and that all required applications are submitted and approved.

These requirements may include that:

i. dispensing pharmacists must not have any undertakings by the Australian Health Practitioner Regulation Agency (AHPRA) on their registration to dispense Schedule 8 products
ii. dispensing pharmacies must meet all requirements and have the appropriate processes for ordering, storing, dispensing, recording, reporting and disposing of unwanted or expired Schedule 8 drugs according to their state or territory legislation
iii. dispensing pharmacists and pharmacy must meet all other state/territory health department specific requirements. These requirements may continue to change so it is necessary to review them regularly.

Examples of specific state/territory health department requirements include:

i. some states provide approval on each occasion an unregistered medicinal cannabis product is to be dispensed
ii. some states may require a pharmacy to obtain the prescription before being able to order the medicinal cannabis product and a pharmacy may need to be nominated by the prescriber or patient
iii. other states may have additional approvals or preparation before pharmacists are ready to dispense medicinal cannabis products. Additional requirement includes state/territory health department endorsement for a nominated pharmacist to dispense medicinal cannabis and to prepare a Medicinal Cannabis Management Plan (MCMP). The state/territory health department must be satisfied with those preparations before authorising the pharmacy to dispense.

For state/territory specific requirements, you can visit the following websites:

- ACT
- Northern territory
- NSW
- Queensland
- South Australia
- Tasmania
- Victoria
- Western Australia

Alternatively, you can access this full list of all health departments.

3. Are any medicinal cannabis products subsidised?

Currently no medicinal cannabis products (registered or unregistered) are subsidised in Australia under the Pharmaceutical Benefits Scheme (PBS). It is recommended that pharmacists check with patients that they understand the costs and are willing and able to pay for the medicinal cannabis product **before** it is ordered by the pharmacy.

4. What should I do if I am presented with a prescription for medicinal cannabis?

a. Confirm that the prescriber is authorised to prescribe medicinal cannabis (some states/territories provide a health department approval number, often written on the prescription), and that the prescription meets all state/territory requirements, noting any additional requirements for Schedule 8 prescriptions. You may need to contact your state/territory health department to confirm the approval.

b. Consider possible adverse effects associated with the prescribed medicinal cannabis when reviewing its use, as well as possible interactions with other medications, and the patient's medical condition(s).

c. If the prescription is for a registered medicinal cannabis product eg, nabiximols (Sativex), order online once affordability has been confirmed with the patient.

d. If the prescription is for an unregistered medicinal cannabis product, you will need to identify the manufacturer or sponsor/supplier. This information may be found on the Special Access Scheme (SAS) or Authorised Prescriber (AP) forms. You may need to contact the prescriber if you have not been provided with a copy of the SAS or AP forms.

e. Once you identify the manufacturer of the prescribed unregistered medicinal cannabis product, you can check the local manufacturer's details and/or the sponsor/supplier (through the Office of Drug Control website).

f. If the product is not available through the sponsor, you need to apply for a licence and a permit in order to import the unregistered medicinal cannabis product from an approved overseas manufacturer.

g. Order the unregistered medicinal cannabis product through the identified sponsor or manufacturer once affordability has been confirmed with the patient. The sponsor/manufacturer will request a copy of the licence and permit approval as well as SAS/AP approval.

h. Once received, store the medicinal cannabis product according to its Schedule requirement until the patient collects the product.

i. Review the use of the medicinal cannabis product with the patient as you would with any other medicine and counsel on safe and appropriate use as prescribed.
j. Ensure you comply with all ordering, supply/dispensing, reporting and monitoring as per your state/territory requirements.

Note: certain states/territories do not allow for the ordering or storage of unregistered medicinal cannabis products in anticipation of a prescription.

5. How do I store medicinal cannabis products?

If the medicinal cannabis product is a Schedule 4 product (ie, total cannabinoid content is 98% or more CBD and 2% or less of other naturally occurring cannabinoids), then it is stored in the same way as other Schedule 4 products as per relevant state/territory legal requirements.

If the medicinal cannabis (registered or unregistered) is Schedule 8, then it is stored in the same way as other controlled Schedule 8 products as per relevant state/territory legal requirements.

- Schedule 8 medicinal cannabis products that require refrigeration, eg, nabiximols (Sativex), must be stored in a lockable refrigerator that is secured to the premises of a pharmacy in the same way as a Schedule 8 safe.
- Alternatively, the refrigerator containing the Schedule 8 medicinal cannabis product must be inside a locked room.
- Access to the Schedule 8 safe, the refrigerator or locked room is restricted to dispensing pharmacists who have no undertakings by AHPRA on their registration to dispense controlled Schedule 8 products.

6. How do I find out what medicinal cannabis can be prescribed for?

The body of evidence is growing for the use of medicinal cannabis for some conditions. However, there have only been a limited number of well-designed clinical trials on medicinal cannabis. The Therapeutic Goods Administration (TGA) has a series of clinical guidance documents developed to assist prescribers who are considering medicinal cannabis for their patients. These clinical guidance documents are available on the TGA online portal.
They provide background information, current evidence for the use of medicinal cannabis in certain conditions, and discuss the quality of evidence available so far for each condition. The NSW Cannabis Medicines Prescribing Guidance is a suite of resources intended to assist medical practitioners in their prescribing and management of cannabis medicines (for NSW patients within current regulatory frameworks and clinical practice).

These guidance documents are available at Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE).

7. Where do I go for more clinical information such as side effects and interactions with other drugs or medical conditions?

Information in this area is developing as evidence grows and clinical experience expands. Therefore, resources traditionally relied upon by pharmacists, including product information (PI) and consumer medicines information (CMI), may not be available for unregistered medicinal cannabis products. Nabiximols (Sativex) is registered on the Australian Register of Therapeutic Goods (ARTG) and has TGA-approved PI and CMI.

Guidance documents provided by the TGA contain some information about adverse effects and drug interactions. However, a pharmacist may:

i. seek relevant pharmaco-therapeutic information about the specific prescribed medicinal cannabis product from the manufacturer or sponsor before, or at the time of, ordering the product
ii. check this information with the prescriber or with their state medicine information centre
iii. check other credible sources of information related to the specific cannabinoid
iv. refer patients to the Medicines Line for information about medicinal cannabis.

Reporting adverse events

It is a requirement of TGA Special Access Scheme category B approval for unregistered cannabis medicines that any events, including anticipated adverse events, are reported to the TGA and the sponsor by the prescriber within 15 calendar days.

For more information visit TGA Special Access Scheme: Guidance for health practitioners and sponsors. 2017

Patients may also report any adverse events by contacting the Adverse Medicine Events Line. Pharmacists may check reported adverse events for medicinal cannabis on the Database of Adverse Event Notification (DAEN) website.

Further information

- Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE)
- Australian Prescriber: Medicinal Cannabis
- NPS medicinal cannabis resources
- NSW Cannabis Medicines Advisory Service
- TGA: Guidance for the use of medicinal cannabis in Australia: Overview