

Supplying medicinal cannabis

Quality use and safety considerations

Best practice principles to guide the safe and effective dispensing and supply of medicinal cannabis to support high-quality patient care.

Key messages

- In Australia, medicinal cannabis products are not recommended as a first-line treatment for any health condition.
- As there are only two products on the [Australian Register of Therapeutic Goods \(ARTG\)](#), most medicinal cannabis products:
 - are unapproved therapeutic goods, and not included in the ARTG
 - have not been assessed by the Therapeutic Goods Administration (TGA) for safety, quality, performance or effectiveness, and
 - should only be considered when all other treatment options are unavailable or unsuitable.
- The quality of evidence supporting medicinal cannabis varies by clinical indication and product type. For many conditions, evidence remains limited and comparative effectiveness relative to established therapies remains uncertain. Medicinal cannabis is not recommended as monotherapy or first-line treatment for any condition in Australia.
- Limited evidence suggests that adjunctive medicinal cannabis may be more effective than placebo in reducing seizures in children with epilepsy.
- Individualised assessment of potential benefit versus harm is required when considering the use of medicinal cannabis.
- Complexity in the supply, handling, storage and labelling of medicinal cannabis products reflects the status of most as unapproved and Schedule 8 (S8) products.
- [Table 1](#) includes quality use and safety considerations as well as risk mitigation actions for the supply of medicinal cannabis products by pharmacists.

Further information is available through the TGA [online portal: Medicinal cannabis - guidance documents](#) and relevant National Board [resources](#) including the [Medicinal cannabis supply](#) guidance.

Purpose

This fact sheet provides best practice principles to support pharmacists in ensuring the safe, appropriate and high-quality supply of medicinal cannabis products across hospital, community and aged care settings. It outlines relevant safety considerations along with relevant legislative requirements to assist pharmacists in the safe supply of medicinal cannabis products as part of broader medication management practices that minimise patient harm.

Scope

This fact sheet applies to the supply of medicinal cannabis products, including the two products on the ARTG and all the unregistered products accessed through the [TGA unapproved access pathways](#) and applies to the practice of all pharmacists. [Table 1](#) includes a list of proposed risks mitigation actions for pharmacists to support safe and appropriate supply of medicinal cannabis. This list is not exhaustive and should be considered alongside other relevant evidence and guidance. This is especially important for specific patient cohorts, such as older people, pregnant and breastfeeding individuals and people with certain medical conditions.

This fact sheet is part of a suite of resources including fact sheets for [prescribers](#) and [nurses](#), which draw on the Australian Commission on Safety and Quality in Health Care's (the Commission's) [Medicinal cannabis safety and quality report](#).

Background

Medicinal cannabis products are therapeutic products that contain or are derived from any part of the *Cannabis* plant and generally contain cannabidiol (CBD) and/or delta-9-tetrahydrocannabinol (THC), or their corresponding acids. There are more than 1,400 different unapproved medicinal cannabis products accessed in Australia with varying CBD and THC content. Medicinal cannabis products are not a single therapeutic entity. CBD and THC have different pharmacological properties, adverse effect profiles and risks. THC containing products are associated with greater risks of cognitive impairment, psychosis, driving impairment and dependence. CBD dominant products generally have a lower risk profile but may still cause adverse effects and clinically significant medicine interactions. Formulations that have been accessed include oral oils, capsules, sublingual products and mucosal sprays.

Medicinal cannabis has been prescribed for use in the following conditions:

- epilepsy
- prevention or management of chemotherapy-induced nausea and vomiting
- multiple sclerosis
- post-traumatic stress disorder (PTSD)
- insomnia
- chronic non-cancer pain, and
- pain and other symptom management in palliative care.

There are currently two medicinal cannabis products included in the [ARTG](#) for specific indications:

- CBD (Epidyolex)
- nabiximols (Sativex Oromucosal Spray).

All other medicinal cannabis products are unapproved, with limited evidence supporting their therapeutic use. As these products have not been assessed by the TGA for safety, quality, performance or effectiveness, they do not have approved Product Information (PI) or Consumer Medicines Information (CMI).

Evidence indicating support for medicinal cannabis is often derived from specific pharmaceutical-grade products and may not be generalised to other commercial products with different formulations, cannabinoid concentrations or routes of administration.



The supply, handling, storage, labelling and administration of medicinal cannabis products are subject to regulatory requirements and guidelines. As most medicinal cannabis products are S8 medicines, these requirements may vary between states and territories.

The key issues

In Australia, medicinal cannabis is not recommended as a first-line treatment for any health condition and should generally be considered only when established treatment options are ineffective, unsuitable or unavailable. It should not be relied upon as the sole therapy for any condition.

Medicinal cannabis can legally be prescribed by medical and nurse practitioners, and designated registered nurse prescribers where authorised under relevant legislation and professional requirements. Designated registered nurse prescribers must prescribe in partnership with an authorised health practitioner in accordance with a prescribing agreement.

However, inappropriate prescribing of medicinal cannabis has been associated with adverse patient outcomes. In addition, adverse effects may occur even when medicinal cannabis is prescribed appropriately.

Many of the products available in Australia contain high concentrations of THC, which may increase the risk of harm, including acute psychosis, cannabis use disorder and impaired driving ability.

Medicinal cannabis should only be considered when all other treatment options are ineffective, unavailable or unsuitable. If an approved ARTG-listed product is not suitable and where clinically appropriate, unapproved products may be accessed via the TGA's [Special Access Scheme \(SAS\)](#), the [Authorised Prescriber \(AP\) Pathway](#) or by participating in a clinical trial. The TGA has resources and guidance on access to approved and unapproved medicinal cannabis products at the [medicinal cannabis hub](#).

Best practice principles for dispensing medicinal cannabis

The following principles provide a guide to safe and effective dispensing of medicinal cannabis:

1. **Check there is a legitimate clinical indication.** Medicinal cannabis is not recommended as first-line treatment for any medical condition in Australia.
2. **Ensure a comprehensive clinical assessment has been completed.**
3. **Be aware of the most evidence-informed indications** (albeit, the evidence is not strong) as follows:
 - Chronic pain (particularly some neuropathic pain)
 - Chemotherapy-induced nausea and vomiting
 - Multiple sclerosis-related spasticity
 - Some refractory epilepsies
 - Palliative care symptom management.
4. **Check for informed consent**, ensuring the patient understands that many products are not approved, their benefits may be uncertain, and adverse effects can occur. Where a patient lacks decision-making capacity, [informed consent requirements](#) should be managed in accordance with relevant substitute decision-making legislation

and local policies. Patients should also be informed that costs are generally not subsidised and that product use may affect their legal ability to drive.

5. **Follow a “start low, go slow” principle**, beginning with the lowest effective dose and titrating gradually. Non-inhaled products such as oils, capsules and oral liquids are preferred over inhaled products with slower onset and longer duration of effect. Smoking is problematic as it is contraindicated in smoke free areas.
6. **Monitor for efficacy and adverse effects** with attention to any cognitive impairment or psychiatric symptoms while looking for symptom improvement and functional outcomes.
7. **Ensure that an exit strategy has been considered** and plan for scenarios where treatment benefits are insufficient, risks outweigh benefits, adverse effects or harm emerge, or misuse is suspected.
8. **Ensure continuity of care**, e.g. coordinating with local primary care services at discharge.

Safe and appropriate supply of medicinal cannabis

Medicinal cannabis products are not a single therapeutic entity. CBD and THC have different pharmacological properties, adverse effect profiles and risks. THC containing products are associated with greater risks of cognitive impairment, psychosis, driving impairment and dependence.

Pharmacists play a critical role supporting safe supply and quality use of medicines across hospital, community and aged care settings. They are well placed to provide education, assess drug suitability and monitor adherence and patient outcomes. [Table 1](#) proposes quality use and safety considerations relevant to the supply of medicinal cannabis products with risk mitigation strategies. Implementation of these measures supports safe and appropriate dispensing in clinical practice, helps minimise potential patient harm and promotes consistency with established clinical and regulatory standards.

Table 1 Quality use and safety considerations and risk mitigation actions for the supply of medicinal cannabis products.

Quality use and safety consideration	Risk mitigation actions for pharmacists
Embed strong governance and oversight frameworks	• Access to medicinal cannabis may be considered only when there is a clinically justified, evidence-based indication and when patients have failed to respond adequately to approved conventional treatments. Pharmacists are expected to keep up to date with current research into medicinal cannabis to inform practice. • Adhere to organisational procedures, statewide or local policies and hospital pharmacy department and/or the drugs and therapeutic committee (or similar) approval processes prior to dispensing medicinal cannabis. For patients in the community or residential aged care facilities, refer to local governance committees and/or community pharmacy policies. • Adhere to the Code of Ethics for Pharmacists.
Participate and maintain workforce capability through education and training	• Complete appropriate education and competency-based training on medicinal cannabis that addresses the pharmacology, product types and dispensing requirements. • Keep up to date with current research into medicinal cannabis to inform safe practice. Completed education and training can be incorporated into an individual pharmacist's continuing professional development (CPD).
Assess regulatory compliance and adhere to legislative requirements	• Use the SAS/AP Scheme Online System which includes a validation tool to verify TGA approval status in real time. If the search does not return a result, contact the prescriber. While approved medicinal cannabis products can be prescribed by medical and nurse practitioners, the AP Pathway for unapproved medicinal cannabis products is available only to medical practitioners. • Confirm prescription compliance with state and territory legislation requirements for medicinal cannabis, including any S8 prescription requirements. • For extemporaneously compounded medicinal cannabis products, adhere to the Pharmacy Board of Australia's Guidelines on compounding of medicines. Extemporaneously compounded medicinal cannabis products can only be supplied on a valid prescription for an individual patient and requires SAS/AP approval prior to preparation by a pharmacist. Pharmacists cannot batch manufacture extemporaneously compounded medicinal cannabis products in anticipation of future demand. For additional information, see Extemporaneous compounding and Extemporaneously compounded medicines. Note unapproved medicinal cannabis products must comply with Therapeutic Goods Order 93 (TGO 93) with TGA guidance Complying with the quality requirements for medicinal cannabis.

Quality use and safety consideration	Risk mitigation actions for pharmacists
Discuss treatment with patient or carer and obtain informed consent	• Check the Real-Time Prescription Monitoring service (RTPM) and My Health Record for relevant patient history. • Collaborate with prescribers and other health professionals, as appropriate, to ensure safe and effective medicine use. • Prioritise person-centred goals around the supply of medicinal cannabis products. • Informed consent must be obtained from the patient (their family or carer) before dispensing a medicinal cannabis product. The patient, their family or carer should be made aware that unapproved medicinal cannabis products are not assessed by the TGA for safety, quality, performance or effectiveness. More information can be found here. • Discuss the treatment plan with the patient, their family or carer including treatment goals, risks, potential adverse effects, route of administration, instructions for appropriate use, titration plan and monitoring of safety and efficacy. • THC containing medicinal cannabis products may be associated with cardiovascular effects including tachycardia, orthostatic hypotension, arrhythmias and acute coronary events. Additional caution may be required in older adults and people with cardiovascular disease. • Caution is warranted in people with a personal or family history of psychosis, bipolar disorder or other serious mental illness, and in adolescents and young adults, as THC containing products may worsen psychiatric symptoms. • Discuss monitoring for potential long-term safety concerns including cognitive impairment, psychiatric symptoms, occupational impairment, reduced functional capacity, dependence, cannabis use disorder and withdrawal symptoms, particularly with THC containing products • Confirm affordability with the patient, their family or carer as most medicinal cannabis products are not subsidised through the Pharmaceutical Benefits Scheme (PBS) and require a private prescription. • Ensure patients have access to, and can appropriately use, any devices required for the safe and effective administration of medicinal cannabis. • Where patients are continuing therapy, reinforce that treatment goals should be specific and measurable (for example, improvement in pain, sleep or function) and reviewed regularly to confirm ongoing benefit. • Encourage discussion of a cessation strategy from the outset, including circumstances in which therapy may need to be reduced or stopped if goals are not achieved, harms emerge or misuse is suspected.

Quality use and safety consideration	Risk mitigation actions for pharmacists
	• In the community setting, verify the patient, their family or carer's understanding of technique when self-administering and provide advice regarding potential driving impairment. • Assess the patient, their family or carer's understanding of therapy, adherence to treatment, and what constitutes a positive clinical response to medical cannabis.
Ensure dispensing practices align with legislative and organisational requirements	• Follow the standards, codes and guidelines established by the Pharmacy Board of Australia. • Comply with established clinical, digital and professional practice standards. • Comply with all legislative and regulatory requirements relating to medicinal cannabis, including those applicable to Schedule 4 (S4) and S8 medicines, and prior to dispensing. Pharmacists must: ○ review patient's medical and medication history ○ check indication, formulation, brand name, strength of each component (such as THC and CBD), dose and dosing frequency, directions for use and quantity for supply ○ ensure clinical appropriateness and check potential drug-drug and drug-disease interactions, particularly when patients are receiving psychotropic medicines, antiepileptic medicines, sedatives, opioids or medicines metabolised through CYP450 pathways ○ check repeat intervals, ensuring these are appropriate and assess for therapeutic duplication when multiple dosage forms or formulations containing the same active ingredient are prescribed, ensuring that concurrent use is clinically appropriate, justified and safe for the patient ○ order through usual pharmaceutical wholesalers if the prescription is for a registered medicinal cannabis product e.g. nabiximols ○ identify the manufacturer or sponsor/supplier if the prescription is for an unapproved product. This information may be found on the SAS or AP application form ○ contact the sponsor to organise supply ○ only order cannabis for compounding from TGA licensed Australian manufacturers or overseas manufacturers with evidence of Good Manufacturing Practice (GMP) in accordance with TGO 93. ○ apply for a licence and a permit if the product is not available through the sponsor to import the unapproved medicinal cannabis product from an approved overseas manufacturer ○ confirm product details and affix a dispensing label in accordance with applicable legislative and professional standards, refer to the National Standard for Labelling Dispensed Medicines

Quality use and safety consideration	Risk mitigation actions for pharmacists
	○ counsel patient or carer and provide written information to ensure safe and effective use of medicinal cannabis including safe storage and disposal and driving precautions. Inform patients of the side effects of cannabinoids including drowsiness and fatigue. Cannabinoids can significantly impair cognitive function and motor coordination; patients should be advised to refrain from driving. Ensure patients are aware of the driving laws in each state and territory and that legally prescribed medicinal cannabis products containing THC may result in driving offences. More information can be found here ○ liaise with the patient's family or carer and usual prescriber to ensure continuity of access to medicinal cannabis products during transitions of care, such as when the patient moves between hospital, community and residential aged care facilities. Medicinal cannabis products are not routinely stocked. Pharmacists should support continuity of supply during admission, discharge and other transitions of care ○ ask the patient or carer to seek advice from their health care professional if their circumstances change. ● Comply with state or territory laws regarding where prescription verification is required for S8 medicines. For instance, contact the prescriber to verify the prescription if it appears to be invalid, clarification is required, jurisdictional legislative requirements are not met, inappropriate use is suspected or if the patient is experiencing adverse effects. For example, a patient with a mental health condition may have worsening psychiatric symptoms, even if they are on an appropriate dose. ● For ongoing or repeat supplies, monitor for long-term safety concerns including sedation, dizziness, cognitive effects, psychiatric symptoms and functional impairment, particularly with THC-containing products. ● Be alert to tolerance, dose escalation, dependence risk or features of cannabis use disorder, and seek prescriber review where treatment is not resulting in improvement of the patient's symptoms or condition, self-escalation or loss of control over use. Ensure that the patient is referred to the prescriber for an individualised plan and monitoring if benefit is limited, harm emerges or misuse is suspected. ● Where a new medicinal cannabis product has been prescribed as a replacement product, or dose reduction or cessation is being considered because of limited benefit or emerging harm, ensure the patient is reviewed by the prescriber for an individualised plan and monitoring for withdrawal symptoms such as sleep disturbance or anxiety. ● Discuss arrangements with patients when product availability changes and options that enable continuity of treatment.

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Maintain safe storage and security	• To prevent diversion, loss or unauthorised access. Pharmacists must: ○ store medicinal cannabis products in accordance with jurisdictional legislative requirements for S8 medicines, refer to Principles for the safe selection and storage of medicines ○ adhere to the prescriber's specified repeat-dispensing interval, as patients are often prescribed multiple medicinal cannabis products that contribute to an overall monthly maximum quantity ○ maintain access controls ○ report and resolve any discrepancies ○ dispose of unwanted or expired medicinal cannabis products according to state or territory legislation ○ confirm that the patient has appropriate arrangements for the safe storage of medicinal cannabis in the home. • Delivery services for dispensed medicinal cannabis products should incorporate appropriate safeguards to ensure secure and timely supply, maintain product quality, protect patient privacy, support continuity of care, and provide patients with access to the information and support needed for the safe and effective use of their medicine.
Implement robust information management processes	• Ensure clear, accurate and up-to-date documentation is maintained including reasons for refusal of supply (if applicable) and any further action taken. • Maintain accurate dispensing records. • Document patient counselling, supply provided and arrangements for safe storage at home to ensure transparency, traceability and continuity of care. • Ensure the patient has an established and timely communication pathway with their prescriber. • Where available, utilise electronic medication management systems to facilitate safe and compliant dispensing of medicinal cannabis products.
Report adverse events	• Report any suspected adverse events resulting from medicinal cannabis use via the TGA's online Adverse Event Reporting portal. Adverse events reported to the TGA are generally included in the publicly available Database of Adverse Events Notifications (DAEN) - Medicines. Reporting of adverse events for unapproved products is encouraged. However, for pharmaceutical companies there are fewer rules requiring the reporting of adverse events, in contrast to registered medicines where there is a regulatory obligation to report. Therefore, the number and nature of the reports for unapproved medicinal cannabis

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	products on the DAEN cannot be used to accurately estimate or compare the safety risks associated with their use. • Report any adverse effects to the prescriber.

Useful resources

- Best Practice Advocacy Centre New Zealand (bpac^{nz}). 2022. [Medicinal Cannabis Special Edition](#).
- Australian Commission on Safety and Quality in Health Care. 2026. [Medicinal cannabis safety and quality report](#).
- Therapeutic Goods Administration. 2025. [State and territory requirements – Applications and reporting for unapproved medicinal cannabis](#)

For more information

Refer to your local medicines and poisons regulator for state/territory medicinal cannabis specific requirements for prescribing, handling, dispensing, administration and use or visit: safetyandquality.gov.au/medicinal-cannabis

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