

Prescribing medicinal cannabis

Quality use and safety considerations

Best practice principles to guide the safe and effective prescribing 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 listed on 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.
- Supply, handling, storage and labelling requirements of medicinal cannabis products are complex as most are unapproved and many are Schedule 8 (S8) products.
- A set of [best practice principles for prescribing medicinal cannabis](#) have been developed for prescribers.
- [Table 3](#) includes quality use and safety considerations as well as risk mitigation actions for the prescribing of medicinal cannabis products.

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 prescribers in the safe and appropriate prescribing of medicinal cannabis across hospital, aged care and community

settings. It outlines relevant safety considerations, risk mitigation actions and prescriber responsibilities to ensure medicinal cannabis is prescribed, supplied and used in accordance with quality use of medicines principles, including judicious and appropriate use.

Scope

This fact sheet applies to the practice of all prescribers prescribing medicinal cannabis products, including the two products on the ARTG and all the unregistered products prescribed through the [TGA pathways](#). [Table 3](#) includes a list of quality and safety considerations and proposed risk mitigation actions for the prescribing of medicinal cannabis products. This list is not exhaustive and should be supported by additional evidence. 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 [pharmacists](#) and [nurses](#) and draws 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 contain or are derived from any part of the *Cannabis* plant and are intended for therapeutic use. They generally contain the components cannabidiol (CBD) and/or 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. Formulations that have been accessed include oral oils, capsules, sublingual products and mucosal sprays. **Table 1** summarises broad differences between CBD and THC components of medicinal cannabis.

Table 1 Characteristics of CBD and THC components of medicinal cannabis.

Characteristic	CBD dominant products	THC containing products
Psychoactive effects	Minimal	Significant
Driving impairment risk*	Lower*	High
Psychosis risk	Minimal	Increased
Abuse and dependence potential	Low	Significant
Typical scheduling	Schedule 4 (S4)	Generally, S8
Adverse effect profile	Sedation, gastrointestinal effects, drug interactions	Sedation, cognitive impairment, psychiatric effects, dependence

*Driving advice should be individualised

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. It should only be considered when established treatment options are ineffective, unsuitable or unavailable. It should not be relied upon as sole therapy for any condition.

Medicinal cannabis may 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.

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 prescribing medicinal cannabis

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

1. **Assess and confirm a legitimate clinical indication.** Medicinal cannabis is not recommended as first-line treatment for any medical condition in Australia.
2. **Conduct a comprehensive clinical assessment.** Document the results in the patient's medical health record.

3. **Be aware of the most evidence-informed indications**, and that the overall quality of evidence remains limited.
4. **Obtain 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 and introduces risk of respiratory complications.
6. **Monitor for adverse effects and efficacy** with attention to any cognitive impairment or psychiatric symptoms while looking for symptom improvement and functional outcomes.
7. **Develop an exit strategy**, planning for scenarios where benefits are insufficient, risks outweigh the benefits, the patient is experiencing adverse effects or showing signs of misuse.
8. **Ensure continuity of care**, e.g. communicating with the patient’s primary health care team at discharge.

Safe and appropriate prescribing of medicinal cannabis

[Table 3](#) identifies quality use and safety considerations relevant to the prescribing of medicinal cannabis products and summarises the corresponding responsibilities and risk mitigation actions for prescribers. Broadly, these follow a monitoring framework described in [Table 2](#).

Table 2 Monitoring framework for medicinal cannabis prescribing

Monitor	Examples
Efficacy	Symptom improvement, quality of life, functional outcomes
Safety	Sedation, dizziness, gastrointestinal effects
Neurocognitive	Concentration, memory, alertness
Psychiatric	Anxiety, mood changes, psychosis
Dependence	Escalating dose request, misuse, withdrawal
Driving and work	Driving ability, safety-sensitive occupations

Implementation of these measures supports safe and appropriate prescribing in clinical practice, helps minimise potential patient harm and promotes consistency with established clinical and regulatory standards.

Table 3 Quality use and safety considerations and risk mitigation actions for the prescribing of medicinal cannabis products.

Quality use and safety considerations	Risk mitigation actions for prescribers
Assess suitability for patient	• Consider all treatment options including non-pharmacological options. Prescribers should only recommend treatments when there is an identified therapeutic need and/or a clinically recognised treatment, and a reasonable expectation of clinical efficacy and benefit for the patient. • Only consider medicinal cannabis when it is clinically justified for an evidence-informed indication and when patients have failed to respond adequately to conventional treatments. • First-line, ARTG-listed medicinal cannabis products should be considered prior to unapproved options. Access to unapproved medicinal cannabis products may only be considered when clinically justified and patients have failed to respond adequately to conventional first-line treatments. Refer to the Commission's Medicinal cannabis safety and quality report. • Prescribers must have adequate knowledge of the medical condition being treated with medicinal cannabis and be satisfied that it is the most appropriate treatment in partnership with their patient. • Collaborate with relevant specialists or consultants when managing complex cases, particularly where multiple prescribers of monitored medicines are involved.
Identify and manage treatment risks	• Assess the benefits vs risks associated with using medicinal cannabis prior to initiation. Unapproved therapeutic goods have not been evaluated by the TGA for safety, quality, performance or effectiveness. Evidence for medicinal cannabis is continually evolving and maintaining awareness of emerging research supports evidence-informed prescribing decisions. • Consider using established screening and assessment tools e.g. Clinical Guidance for the Use of Medicinal Cannabinoids in the Management of Chronic Non-Cancer Pain in Veterans includes a clinical assessment and prescribing protocol to support decision making prior to prescribing medicinal cannabis for veterans with chronic non-cancer pain. • Be aware of potential side effects of medicinal cannabis which may include central nervous system and gastrointestinal effects. Responses vary across individuals; the nature and severity of side effects may differ and are generally dose dependent. In general, the side effects of products with THC are more impactful than those for products containing CBD alone. • Medicinal cannabis, particularly THC-containing products, may be associated with cardiovascular effects including tachycardia, orthostatic hypotension, arrhythmias and acute coronary syndromes. Caution is recommended in older adults and those with established cardiovascular disease or significant cardiovascular risk factors.

Quality use and safety considerations	Risk mitigation actions for prescribers
	• Assess potential interactions with other medicines before initiating or reviewing medicinal cannabis treatment and monitor patients' response throughout therapy. Medicinal cannabis may interact with a range of medicines including antiepileptic medicines, psychotropic medicines, opioids, sedatives and medicines metabolised through CYP450 pathways. • 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. • For patients established on medicinal cannabis, monitor long-term safety and evolving health risks, including cardiovascular and neurocognitive effects, psychiatric symptoms (including psychosis, severe anxiety and substance use disorder) and functional impairment. • Caution should be taken in patients with a history of mental health illness. Higher THC exposure has been associated with an increased risk of psychotic symptoms and worsening of existing psychiatric illness. Caution is required when considering THC-containing medicinal cannabis products in: ○ adolescents and young adults ○ patients with a personal history of psychosis ○ patients with a family history of psychosis ○ patients with bipolar disorder ○ patients with severe anxiety disorders. • The long-term safety and effectiveness of medicinal cannabis is not established and may include cognitive impairment, dependence, cannabis use disorder, withdrawal symptoms, occupational impairment and reduced functional capacity. At treatment initiation, prescribers should establish clear treatment goals and criteria for review, dose tapering and cessation. • Closely monitor for the development of tolerance and dependence and implement clear prescribing limits. • To minimise the risk of adverse effects, reassess the ongoing need for medicinal cannabis based on outcome benefit for the medical condition or clinical indication. • Assess and manage dependence and cannabis use disorder, particularly with long-term or higher-dose use. Include a cessation strategy or deprescribing plan and consider dose reduction or cessation if benefit is limited, harm emerges or misuse is suspected. • Exercise caution when prescribing a new medicinal cannabis product as a replacement product where treatment response is inadequate or tolerability issues occur.

Quality use and safety considerations	Risk mitigation actions for prescribers
Obtain a complete and accurate patient history and undertake a comprehensive clinical assessment	• Conduct and document the results of a comprehensive clinical evaluation or assessment of the patient prior to commencing medicinal cannabis, including but not limited to their: ○ clinical presentation and diagnosis ○ physical and mental state examination ○ medical history: patient and family history of mental illness especially schizophrenia, psychosis, bipolar disorder, drug dependence or substance abuse, cardiovascular, hepatic or renal disease ○ medication review: potential interactions with existing medicines, in particular medicines that are involved in the cytochrome P450 (CYP450) enzymatic pathway ○ type of employment (e.g. operating machinery), family responsibilities, need to drive and social support.
Discuss treatment with the patient or carer and obtain informed consent	• Prioritise person-centred goals around the presenting diagnosis. • Obtain informed consent from the patient, family or carer before prescribing medicinal cannabis. They must be made aware that unapproved medicinal cannabis products are not assessed for safety, quality, performance or effectiveness. The discussion can be facilitated by use of patient information and include the potential risks and uncertainties associated with treatment, and the patient, their family or carer's understanding of these matters should be documented. • Discuss treatment options with the patient or carer including clinical reasons for prescribing medicinal cannabis; treatment goals, risks and potential side effects; the route of administration and instructions for use; the titration plan and potential exit strategy; and the need to monitor safety and efficacy. • Assess and document the alternative conventional treatment options that have been tried and failed or considered, and if prescribing a medicinal cannabis product that is not registered on the ARTG, document the reasons for its selection. • Ensure patients have access to, and can appropriately use, vaping devices included on the ARTG required for the safe and effective administration of medicinal cannabis. • Discuss an exit strategy from the outset, including circumstances in which therapy may need to be reduced or stopped if treatment goals or benefits are not being achieved, adverse effects or harms emerge, or misuse is suspected.
Ensure the product is available and affordable for the patient	• Ensure that appropriate arrangements are in place for the supply of medicinal cannabis and the location of dispensing is nominated. Access is especially important at transitions of care. People who use medicinal cannabis in the community may experience challenges when admitted to hospital as medicinal cannabis products are not

Quality use and safety considerations	Risk mitigation actions for prescribers
	routinely stocked by hospitals. Prescribers should consider continuity of supply and treatment arrangements during hospital admission, discharge and other transitions of care. Confirm the affordability for the patient as most medicinal cannabis products are not subsidised through the Pharmaceutical Benefits Scheme (PBS) and only supplied on a private prescription.
Comply with established clinical, digital and professional standards	- Prescribers (medical practitioners, nurse practitioners and designated registered nurse prescribers) must maintain high standards of clinical practice and professional conduct when prescribing medicinal cannabis, comply with all relevant standards, codes and guidelines established by their National Board and adhere to the National Prescribing Competencies Framework. - Nurse practitioners and designated registered nurses prescribers should also refer to the relevant standards, codes and guidelines established by the Nursing and Midwifery Board of Australia. - Prescribers are encouraged to use electronic medication management systems and other prescribing software configured to facilitate safe and compliant prescribing of medicinal cannabis. - Prescribing of medicinal cannabis via telehealth must be undertaken in accordance with relevant telehealth guidelines and regulatory requirements. - Prescribers should only prescribe products that comply with the quality requirements for medicinal cannabis as set out in Therapeutic Goods Order 93 (TGO 93).
Participate and maintain workforce capability through education and training	- Complete appropriate education and competency-based training on medicinal cannabis. Prescriber specific education and training should cover regulatory requirements, evidence base, patient selection, product types, dosing, monitoring, adverse effects, drug interactions, and safe prescribing practices associated with medicinal cannabis focussing on informed decision-making and appropriate patient care. - Prescribers are expected to keep up to date with medicinal cannabis research to inform safe practice. Completed education and training can be incorporated into an individual prescriber's continuing professional development (CPD).
Ensure prescriptions meet legal and state and territory regulatory requirements	- Use the SAS/AP Scheme Online System to seek approval to prescribe unapproved medicinal cannabis products, having first considered other appropriate treatment options included in the ARTG. - Adhere to state and territory requirements to prescribe medicinal cannabis including Real Time Prescription Monitoring (RTPM) and updating a person's My Health Record.

Quality use and safety considerations	Risk mitigation actions for prescribers
	- Where medicinal cannabis is being prescribed for the management of dependence or substance use disorders, ensure any additional state or territory approvals, permits or specialist authorisations required within the jurisdiction have been obtained before treatment commences. - Obtain hospital pharmacy department (or similar) approval prior to prescribing medicinal cannabis to patients while they are in hospital. For patients in the community or residential aged care homes, refer to the relevant facility governance committee and/or community pharmacy. - When all required approvals, either for an unapproved product or an S8 medicine, have been received, a prescription can be issued by the prescriber. All legislative and regulatory requirements relating to medicinal cannabis, including those applicable to S4 and S8 medicines must be met. Prescribers must include: - active ingredient(s), formulation, strength(s) of each component (such as THC and CBD) - name of proprietary product; while not mandatory, it is highly recommended - dose and frequency of administration - exact directions for use - quantity of supply - number of repeats.
Maintain comprehensive medical records and devise a patient treatment plan	- Assess the patient, family or carer's understanding, patient concordance and response to medicinal cannabis. - Ensure clear, accurate and up-to-date medical documentation is maintained. - Set and review measurable treatment goals at appropriate intervals. Ongoing therapy requires regular reassessment of clinical need and therapeutic benefit against these goals. - Document monitoring requirements and review frequency, including efficacy, adverse effects, function and potential interactions with the patient's other medicines. - Include a communication plan to ensure timely and effective communication with the patient's regular health care professionals (such as specialists, general practitioner, pharmacist). - Consider cessation of treatment if treatment goals or benefits are not being achieved, adverse effects or harms emerge, or misuse is suspected, and have a tapering plan in place. If required develop a cessation strategy or deprescribing plan.

Quality use and safety considerations	Risk mitigation actions for prescribers
Report adverse events	• Prescribers of unapproved medicinal cannabis products accessed through the TGA SAS or AP Pathway should report suspected adverse events and product defects to the TGA in accordance with relevant reporting requirements. • Report any suspected adverse events resulting from medicinal cannabis use to the TGA's 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 products on the DAEN cannot be used to accurately estimate or compare the safety risks associated with using them. • Report concerns regarding misuse to other treating specialists including patients' usual prescriber, general practitioner and dispensing pharmacist.

Useful resources

- Australian Commission on Safety and Quality in Health Care. 2026. [Medicinal cannabis safety and quality report](#).
- Australian Health Practitioner Regulation Agency (AHPRA). 2025. [Australian Health Practitioner Regulation Agency - Medicinal cannabis prescribing](#).
- Best Practice Advocacy Centre New Zealand. 2022. [Medicinal Cannabis Special Edition](#).
- [Therapeutic Goods Administration \(TGA\) - Medicinal cannabis hub](#)
- Therapeutic Goods Administration (TGA). [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 or visit safetyandquality.gov.au/medicinal-cannabis

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