

Medicinal cannabis

Safety and quality report

This report has been developed by the Australian Commission on Safety and Quality in Health Care (the Commission) to support clinicians on the quality use and safety considerations associated with medicinal cannabis in clinical practice.

Purpose

This report builds on previously published evidence and summarises a review of the literature from 2020 to 2025 of evidence for safe and effective use of medicinal cannabis. The evidence base for medicinal cannabis continues to evolve, and emerging evidence may inform future updates to the findings presented in this report.

The Commission has published fact sheets for [prescribers](#), [pharmacists](#) and [nurses](#) on the quality use and safety considerations when using medicinal cannabis.

Key messages

- In Australia, medicinal cannabis products are not recommended as a first-line treatment for any health condition.
- 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.

- There is no high-quality evidence to support using medicinal cannabis as a monotherapy or first-line treatment for:
 - epilepsy
 - multiple sclerosis
 - chronic non-cancer pain
 - pain and other symptom relief in palliative care
 - post-traumatic stress disorder (PTSD)
 - insomnia
 - prevention or management of chemotherapy-induced nausea and vomiting.
- 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 products.

Background

Medicinal cannabis products are products intended for therapeutic use that contain or are derived from any part of the *Cannabis* plant. They generally contain the components cannabidiol (CBD) and/or delta-9-tetrahydrocannabinol (THC) or their corresponding acids in varying proportions. Common dosage forms for medicinal cannabis are oral products, particularly oral oils, capsules and mucosal sprays.

Regulation

In February 2016, amendments to the *Narcotic Drugs Act 1967* allowed the supply of medicinal cannabis for the management of certain medical conditions. The TGA regulates medicines in Australia and assesses the quality, safety and efficacy of medicines as described in Australia's [National Medicines Policy](#).¹

There are two approved medicinal cannabis products on the [Australian Register of Therapeutic Goods](#) (ARTG):

- Epidyolex® (CBD), which is approved for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients 2 years of age and older
- Sativex® (nabiximols), which is approved for moderate to severe spasticity due to multiple sclerosis.

Most medicinal cannabis products are unapproved therapeutic goods, not included in the ARTG. They have not been assessed by the TGA for safety, quality, efficacy (performance) or effectiveness and should only be considered when all other treatment options are unavailable or unsuitable.² Access to unapproved medicinal cannabis products is regulated by the TGA through the [Special Access Scheme \(SAS\)](#) or the [Authorised Prescriber \(AP\) Pathway](#). The SAS allows access to unapproved therapeutic goods for individual patients, whereas the AP Pathway enables approved clinicians to prescribe an unapproved product to multiple patients with the same medical condition or for the same indication. The prescribing health practitioner

takes responsibility for the use of an ‘unapproved’ therapeutic good and outcomes, including any associated adverse reactions.

TGA has resources and guidance on access to approved and unapproved medicinal cannabis at their [medicinal cannabis hub](#).

CBD only products are Schedule 4 medicines however most other products including all which contain THC are Schedule 8 medicines. Access controls are applied under state and territory [laws](#).

Clinical perspective

In Australia, medicinal cannabis products are not recommended as a first-line treatment for any health condition. The [TGA website](#) provides an overview of guidance for the use of medicinal cannabis in Australia.

There is low consumer awareness about the quality and safety implications of using unapproved, medicinal cannabis. In addition, the limited availability of evidence-based information increases potential for misinformation and harm.

There is a growing number of online medicinal cannabis services that prescribe and/or dispense. Some medicinal cannabis services promote consultations and access pathways to the Australia public. The significant risks to safety and quality include:

- limited ability to conduct a comprehensive medical assessment
- time constrained consultations
- limited assurance that patient informed consent is obtained
- limitations in scope of practice
- limited capacity to obtain complete medical history or current medicines list
- limited capacity to monitor for desired outcome or adverse effects
- barriers to use of Real-time Prescription Monitoring; patients may live in a different state or territory to the prescribing service
- limited capacity to provide continuity of care through communication with the patient's regular clinicians and the sharing of information through shared patient health records
- limited access to a patient's comprehensive health and medication history
- potential for limited oversight from the person's regular general practitioner.

In November 2024, the New South Wales Ministry of Health released a [guide to medicinal cannabis use and public safety considerations](#).

In April 2025, the Royal Australian College of General Practitioners (RACGP) updated its advice on the [use of medicinal cannabis products](#), highlighting, the need for further high-quality research into the safety and effectiveness of medicinal cannabis products, as the evidence is limited and inconclusive.

In July 2026, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) released a [clinical memorandum](#) stating that, despite growing public and medical interest, evidence for the efficacy and safety of medicinal cannabis products in neuropsychiatric and neurodevelopmental disorders in children and adolescents remains limited.

Evidence for safe, effective and quality use of medicinal cannabis

Efficacy

The evaluation from 2020 to 2025 demonstrated favourable effects for use of medicinal cannabis in paediatric epilepsy compared to placebo. There was no high-quality evidence demonstrating a clinical benefit of medicinal cannabis in chronic non-cancer pain, adult epilepsy, nausea and vomiting, multiple sclerosis, palliative care, PTSD and insomnia. For the majority of studies, the exact proportions of the medicinal cannabis components were not reported.

Most available studies compare medicinal cannabis to placebo. However, there is a paucity of evidence comparing medicinal cannabis with first-line treatments, despite the availability of evidence-based therapeutic alternatives for all indicated conditions.

Moreover, there is no high-quality evaluation of a specific medicinal cannabis compound in a standardised formulation or dosage regimen. Across the studies reviewed, the type, strength and formulation of the medicinal cannabis product varied. The components CBD and/or THC, or their corresponding acids, were present in varying amounts, either singly or in combination.

Overall, the evidence continues to align with previously [published guidance](#). There was no high-quality evidence reporting on the safety of medicinal cannabis in long-term use. No studies assessing the long-term safety of medicinal cannabis were identified. The side effect profile of medicinal cannabis is influenced by the formulation of choice.

[Table 1](#) compares efficacy evidence (2020 to 2025) by indication from the literature review with evidence and recommendations published by the TGA in 2020.

Safety

Medicinal cannabis products vary in their THC and CBD content. It is important to understand the active ingredients and their strength in each product to understand the benefit to risk profile, to minimise harm and the potential for interaction with other medicines.

Medicinal cannabis is associated with side effects that include dizziness, drowsiness, nausea, and impaired memory and concentration.³ Medicinal cannabis may increase the risk of adverse cardiovascular effects, particularly in those with a history of cardiovascular disease. It may also worsen mental health conditions such as anxiety, psychosis or mood disorders, especially in susceptible individuals or at higher THC doses.^{4,5} The long-term safety is unknown⁶ and long-term use is not recommended. A deprescribing or cessation plan should be established at the commencement of treatment and reviewed regularly throughout therapy.

Additional considerations are required if prescribing for certain patient cohorts, including children and adolescents, older adults, pregnant or breastfeeding women.^{3,4} Moreover, medicine orders and the management of medicines at transition of care should clearly describe all medicines, including prescription, complementary and alternative, and over the counter medicines. The composition of any medicinal cannabis product should be described in medicine orders and communicated clearly at transitions of care.

Quality

The supply of unapproved medicinal cannabis is increasing. At present, this is mostly through the SAS and AP Pathway. While the schemes provide consumer access, they also allow supply of products that have not undergone full regulatory assessment by the TGA for safety, quality, efficacy and effectiveness. If a non-ARTG medicinal cannabis product is prescribed, the prescriber must document in the patient's medical record the alternative treatment options

considered and the reasons they were deemed clinically inappropriate. Additionally, it is essential that consumers provide informed consent when they are prescribed and dispensed unapproved products, including understanding that benefits and harms may be unknown.²

There is some complexity in navigating regulatory requirements and guidelines for the supply, handling, storage and labelling of medicinal cannabis products, given most products are Schedule 8 medicines, which vary across the states and territories. For example, most products are non-compliant with [Therapeutic Goods Order 91 \(TGO 91\) Standard for labels of prescription and related medicines](#). Additionally, medication management for people presenting with medicinal cannabis products in various care settings such as aged care homes and hospitals and when transitioning between care settings introduces further complexities. Patients transitioning from community to hospital settings may encounter challenges accessing medicinal cannabis, as many hospitals do not routinely stock medicinal cannabis products. Patients with planned hospital admissions should consult their prescriber prior to admission to discuss continuity of treatment.

In August 2025, the TGA commenced a [consultation](#) on reviewing the safety and regulatory oversight of unapproved medicinal cannabis products to gather information on stakeholders' experiences, observations and knowledge to inform regulatory reform. Several issues have been identified in relation to the use and management of unapproved medicinal cannabis products in Australia. The [Commission's response](#), highlighted overarching safety and quality issues relevant to the use of medicinal cannabis products.

1. Identification and labelling of medicinal cannabis products

Consistent and standardised identification of medicinal cannabis products is essential to support safe prescribing, dispensing and administration. Variation in naming leads to inconsistencies in prescribing, medication reconciliation and documentation. It presents unique challenges at transitions of care.

All medicinal cannabis products should be described and labelled clearly identifying the active ingredient name(s) for example, THC and CBD, in addition to the brand name. Labels should also clearly specify the dosage form, route of administration and the strength of each active ingredient in milligrams per unit, as per usual standard of other Schedule 4 and Schedule 8 medicines.

Medicinal cannabis products should also be allocated an [Australian Medicines Terminology](#) (AMT) code to support standardised naming and safe prescribing, dispensing and clinical documentation in electronic medication management systems.

2. Standardised access

Regulatory requirements for prescribing, supply, storage, dispensing, labelling and disposal vary across Australian states and territories. These jurisdiction-specific requirements must be considered and complied with when managing medicinal products. Moreover, variation in prescribing across access pathways presents challenges at transitions of care.

3. Increased adverse event reporting

Sponsors or manufacturers of medicinal cannabis products are encouraged to report adverse events to the TGA. However, they are not required to report these events unless they are also the prescriber. This differs from medicines included in the ARTG, where mandatory adverse event reporting obligations apply. There is a significant growth in SAS and AP approvals for unapproved medicinal cannabis products which represents a risk to consumers. However, this provides information on the safety profile of medicinal cannabis products.

4. Information on contraindications and special precautions

Provision of information on contraindications and special precautions is limited for medicinal cannabis products. Unlike with products included in the ARTG, sponsors or manufacturers are not required to produce product information for approval by the TGA. Acknowledging the background of limited high-quality safety and efficacy evidence for medicinal cannabis, overarching guidance for use in specific populations such as neonates, children and adolescents, older adults, pregnant and breastfeeding women would support clinicians to make safer prescribing decisions in these populations.

Literature review

In 2017, the Department of Health, Disability and Ageing (the Department) developed [a series of guidance documents](#) to assist health professionals and patients, who choose to access unapproved medicinal cannabis in Australia. These relate to use of medicinal cannabis in the treatment of palliative care, epilepsy, chemotherapy-induced nausea and vomiting (CINV), multiple sclerosis (MS) and chronic pain. In 2020, the National Drug and Alcohol Research Centre (NDARC) reviewed the clinical evidence for the use of medicinal cannabis and additional relevant studies were included for epilepsy and pain. In 2024, the Department's guidance documents were updated.

The Commission leads and coordinates key improvements in safety and quality in health care across Australia. The Commission's Health Services Medication Expert Advisory Group (HSMEAG) and Medication Safety and Quality Advisory Committee (MSQAC) jointly requested the Commission identify and appraise the evidence for the use of medicinal cannabis products in the published literature from 2020 to 2025. Acknowledging the TGA regulates the safety, quality and efficacy of medicines, the objective of the review was to understand the environment, trends, behaviours and practices relating to medicinal cannabis and the implications for safe and quality use. The review, reported here, was conducted by the Quality Use of Medicines and Pharmacy Research Centre at the University of South Australia (Adelaide University).⁷

This report summarises the evidence from systematic reviews or meta-analyses published from 2020 to 2025, building on the 2020 TGA guidance. Aligned with the 2020 NDARC update, the review focused on the efficacy and safety of medicinal cannabis in epilepsy, multiple sclerosis, chronic non-cancer pain, palliative care and prevention or management of chemotherapy-induced nausea and vomiting in cancer. The review also considered evidence for two additional indications post-traumatic stress disorder (PTSD) and insomnia.

Future considerations

There is a need for further high-quality research into the safety and effectiveness of medicinal cannabis products, as the evidence does not support the current volume of use. It is essential that clinicians are informed about the evidence of benefits and harms of unapproved products, have clear advice on access pathways and are supported to make decisions in partnership with consumers if using medicinal cannabis products. Clinicians providing virtual care should be aware of their professional, legal and regulatory obligations, particularly where there is limited access to the patient's clinical history, health information or previous care records.

Table 1 Efficacy evidence summary by indication from 2020 to 2025 compared to evidence by the TGA in 2020.

Indication	Evidence from TGA 2020 guidance with recommendations	Summary of evidence for effectiveness 2020 to 2025	Additional information/comments
Epilepsy in children	- Limited high-quality evidence - No comparative data with active comparators <u>Recommendation:</u> Treatment with CBD recommended as an adjunct to existing anti-epileptic drugs.	- Favourable effects were found for use in childhood epilepsy compared to placebo - No new evidence was identified for use compared to active comparators.	Medicinal cannabis demonstrated at least 50% reduction in seizure frequency when compared to placebo for the treatment of Dravet Syndrome, Lennox-Gastaut Syndrome and Tuberous Sclerosis Complex. ⁸
Prevention or management of chemotherapy induced nausea and vomiting in cancer (CINV)	- No high-quality evidence - No comparative data with available antiemetics <u>Recommendation:</u> Treatment should only be considered after accepted clinical management strategies have been appropriately followed and found to be ineffective, with treatment decisions based on an individual assessment of the potential benefits and risks, noting the limited evidence supporting its use for the prevention of nausea and vomiting.	No new evidence was identified for use in CINV compared to placebo or active comparators.	
Multiple sclerosis (MS)	In the absence of evidence comparing its use to first-line treatments, no basis for using it as monotherapy or first-line <u>Recommendation:</u> Nabiximols or dronabinol may be used as an adjunctive therapy.	No new evidence was identified for use in MS compared to placebo or active comparators.	

Indication	Evidence from TGA 2020 guidance with recommendations	Summary of evidence for effectiveness 2020 to 2025	Additional information/comments
Chronic non-cancer pain (CNCP)	- Most evidence is from studies derived for its adjuvant role - Its place in the therapeutic hierarchy was not reported or could not be determined <u>Recommendation:</u> Not to replace current first-line treatments. There is significant potential for drug interactions which needs further study.	No new evidence was identified for use in CNCP compared to placebo or active comparators	Meta-analyses for the use of medicinal cannabis in CNCP demonstrated statistically significant effects compared with placebo. However, the magnitude of effect did not reach thresholds considered clinically meaningful. ^{9,10}
Palliative care	- Few studies exist - Possible interactions with chemotherapy and other medicines <u>Recommendation:</u> Should be used only after standard treatments have failed.	No new evidence was identified for use in palliative care compared to placebo or active comparators.	
Post-traumatic stress disorder (PTSD)	No guidance from TGA.	No evidence identified for use for symptoms of PTSD compared to placebo or active comparators.	One systematic review included studies on mood disorders, anxiety disorders and PTSD.
Insomnia	No guidance from TGA.	No evidence identified for use in insomnia compared to placebo or active comparators.	Meta-analytic evidence comparing medicinal cannabis to placebo for insomnia demonstrated statistically significant effects for reported sleep quality and sleep disturbance. However, the improvement on sleep was small and did not reach the threshold considered clinically meaningful to patients. ^{6,11}

Useful resources

- Australian & New Zealand College of Cannabinoid Practitioners (ANZCCP). General Guidance Document for Prescribing, Dosing, and Titration of Medicinal Cannabis for Health Care Professionals (HCPs). ANZCCP. Available from: https://anzccp.org/?s=guidance&e_search_props=9e30b92-7413 [Cited 10 February 2026].
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For more information

Please visit: safetyandquality.gov.au/medicinal-cannabis



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Disclaimer: This report reflects the research, regulatory and clinical context based on the best available evidence as of September 2025. This document is intended to support clinicians in assessing safety and quality when considering prescribing, dispensing or administering medicinal cannabis. It does not replace clinical judgment, individualised patient assessment or compliance with legislative and regulatory requirements. Evidence and guidance may change; users should consult current information.