Medico-legal considerations when prescribing medicinal cannabis products

Reading time:
Dr Owen Bradfield Chief Medical Officer of MIPS
Date created: 06/10/2025

The cannabis plant contains hundreds of bioactive molecules, of which tetrahydrocannabinol (THC) and cannabidiol (CBD) are the most studied. THC and CBD have distinct but overlapping therapeutic applications, including in modulating pain, sleep, appetite, and mood. While THC can have an intoxicating effects, CBD is thought not to.

In 2015 and 2016, the Commonwealth government rescheduled CBD and THC for medicinal purposes amidst pressure for reform by state governments, patients and the media. In 2021, further changes allowed greater access through the Authorised Prescriber Scheme (described below). Since then, there has been an increase in the number of people receiving prescriptions for medicinal cannabis and the number of practitioners prescribing medicinal cannabis. In 2022-23, it was estimated that 3% of the population had used medicinal cannabis.

Unsurprisingly, MIPS has also seen an increase in the number of claims and complaints arising from medicinal cannabis prescribing. Medicinal cannabis prescribing and advertising (particularly via telehealth) is now an area of regulatory focus for Ahpra and the Medical Board of Australia. This article sets out the main medicolegal considerations to consider.

Prescribing requirements

When prescribing medicinal cannabis products, practitioners must be aware of the need to comply with **both** Commonwealth and State/Territory prescribing requirements.

1. **Commonwealth requirements – approval by the Therapeutic Goods Administration**

There are currently more than 1000 medicinal cannabis products supplied in Australia. Only **two** have undergone pre-market assessment and been approved by the Therapeutic Goods Administration (TGA) to establish their quality, safety, efficacy and performance. They are:

Approved product	Description	Approved use
Nabiximols (Stativex)	Spray containing equivalent amounts of THC and CBD	Spasticity in Multiple Sclerosis
Cannabidiol (Epidyolex)	A solution containing CBD only	Rare and severe forms of epilepsy in children >2 yrs

All other medicinal cannabis products are not TGA approved and can only be prescribed with specific authorisation from the TGA, either through the Special Access Scheme (for individual patients) or the Authorised Prescriber Scheme (for multiple patients with specific conditions).

The **Special Access Scheme** allows practitioners to apply online to prescribe medicinal cannabis for each patient. A copy of the application and approval should be kept in the patient's medical record.

The **Authorised Prescriber scheme** allows practitioners to apply online to prescribe medicinal cannabis products without the need for individual approvals for every patient. The approval lasts for five years, but practitioners must report numbers of patients prescribed medicinal cannabis every six months

Currently, more than 99% of prescriptions in Australia are for unapproved medicinal cannabis products. According to the TGA, patients and prescribers often erroneously assume that products accessed through the Special Access Scheme or the Authorised Prescriber Schemes have been evaluated for safety and approved by the TGA.

2. **State/Territory requirements**

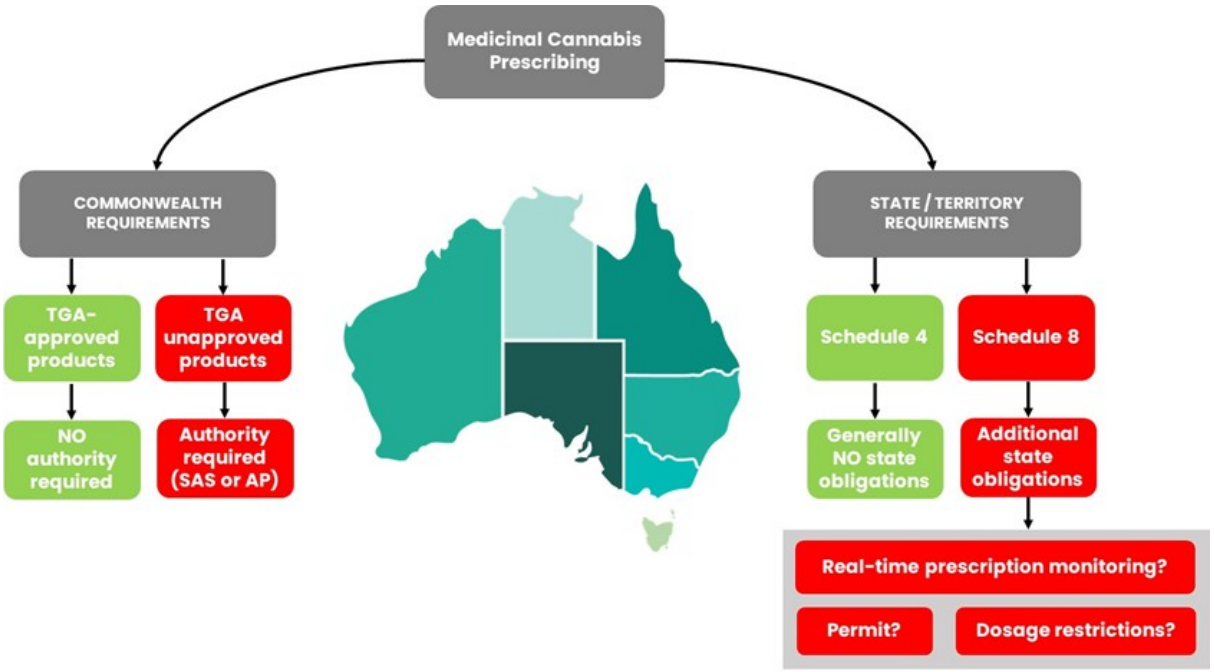
In addition to obtaining TGA approval (where required), practitioners must also comply with state/territory requirements for prescribing medicinal cannabis products. Requirements differ across states/territories and depend on whether the specific medicinal cannabis product is classed as a Schedule 4 or Schedule 8 medicine. There are five categories of medicinal products, four of which are categorised as Schedule 8.

Category	Description	THC content	Schedule
1	CBD medicinal cannabis product	<2%	Schedule 4
2	CBD-dominant medicinal cannabis product	2-40%	Schedule 8
3	Balanced medicinal cannabis product	40-60%	Schedule 8
4	THC-dominant medicinal cannabis product	60-98%	Schedule 8
5	THC medicinal cannabis product	>98%	Schedule 8

The following table summarises the requirements in each jurisdiction for prescribing Schedule 8 medicines.

State/Territory	Requirements
Australian Capital Territory	Prescribers of Schedule 8 medicinal cannabis products require approval from the Chief Health Officer where the patient: • is drug dependent • has been prescribed the Schedule 8 medicinal cannabis product within the previous 2 months • is expected to require treatment for longer than 2 months. More information can be found here.
New South Wales	An approval is only required from the NSW Ministry of Health if the patient is drug-dependent. Otherwise, prescribers must practice within their scope; assess evidence before prescribing an unapproved product; consider other TGA-approved treatment options before applying to access to unapproved products; and establish whether the patient is being supplied any other Schedule 8 medicine (such as by checking SafeScript NSW). More information and guidance is available.
Northern Territory	Information for prescribers can be found here. Authorisation from the Northern Territory government is not required prior to prescribing a Schedule 8 medicinal cannabis product. Notification to the Chief Health Officer if treatment with Schedule 8 medicinal cannabis is successful and the patient will be receiving the medicine for more than two months. Notification is not required for Schedule 4 medicinal cannabis.
Queensland	Information for prescribers can be found here. Prescribers must check Queensland's real-time prescription monitoring database (QScript) and comply with the Monitored Medicines Standard.
South Australia	A South Australian authority to prescribe a Schedule 8 medicinal cannabis product is required: after 2 months of treatment or before commencing treatment where the person has already been prescribed a Schedule 8 drug for a period exceeding 2 months; or before commencing treatment for any drug-dependent person. More information can be found here.

Tasmania	Information can be found here. An authorisation under Section 59E of the Tasmanian Poisons Act 1971 is required prior to issuing a prescription for a Schedule 8 medicinal cannabis product for each individual patient. No Tasmanian authorisation is required for Schedule 4 medicinal cannabis products.
Victoria	Prescribers and pharmacists are required to check SafeScript prior to prescribing and dispensing Schedule 8 medicinal cannabis products to any patient. A permit is required if the patient has a history of drug-dependence. No additional obligations for Schedule 4 medicinal cannabis. More information can be found here.
Western Australia	Prescribers in WA do not require CEO authorisation when prescribing Schedule 8 medicinal cannabis where specific prescriber, patient and product criteria are met. See recent MIPS guidance for a summary. More information can be found on the WA Department of Health website here.



In all Australian States and Territories except for ACT, NSW and WA, it is mandatory to check the real-time prescription monitoring database in that jurisdiction before prescribing a Schedule 8 medicinal cannabis product. In ACT, NSW and WA, it is highly recommended.

Telehealth

Most medicinal cannabis prescribing claims seen by MIPS are in the context of a telehealth consultation. Practitioners prescribing medicinal cannabis via telehealth need to be satisfied that this medium is appropriate and facilitates adequate assessment of the clinical need and risks before prescribing. Practitioners need to consider whether a brief virtual assessment is sufficient to understand a patient's mental and substance use history.

In addition, the Medical Board of Australia's recently updated telehealth guideline states that prescribing or providing healthcare without a real-time consultation (a practice known as "asynchronous telehealth") is not good practice and is not supported by the Board. Asynchronous telehealth includes requests for medication communicated by text, email, live chats or online, where the practitioner has never spoken to the patient.

The other challenge of prescribing medicinal cannabis using telehealth is that practitioners may need to comply with prescribing requirements in the state or territory where the practitioner, patient and/or dispensing pharmacy is physically located. Many of the regulatory notifications received by MIPS members relate to non-compliance with interstate prescribing requirements – in

particular, failure to check real-time prescription monitoring databases.

Consent

As all but two medicinal cannabis products are unapproved by the TGA, they have not been tested for safety or quality. It is essential that patients are fully informed about the untested and unapproved nature of products prescribed. Similarly, it is essential to provide balanced information about the emerging nature of the evidence for the use of medicinal cannabis for a number of clinical conditions. Any information provided and the patient's consent (or refusal to consent) to the prescription of medicinal cannabis should be documented in the medical record.

Advertising

Some practices and practitioners have been fined by the TGA and investigated by medical regulatory bodies for breaches of advertising standards. It is an offence to advertise prescription-only medicines (such as medicinal cannabis) directly to consumers, as it may create inappropriate demand and lead to unnecessary or harmful prescribing. Serious penalties can apply, including fines or civil or criminal court action. Ahpra's Advertising Guidelines also require practitioners to only publish fair, balanced and evidence-informed information to the public that does not create unnecessary demand for regulated health services.

Communication with regular treating practitioners

Some practitioners have received regulatory notifications made by patients' regular treating practitioners who were unaware that their patient had been prescribed medicinal cannabis and considered the prescribing to be clinically inappropriate. MIPS strongly recommends that any practitioner considering prescribing medicinal cannabis seek consent from patients to discuss the proposed prescribing with the patient's regular treating practitioner and that good medical practice involves obtaining a thorough medical history (including from regular treating practitioners) before prescribing.

Driving and medicinal cannabis

All Australian states and territories (except for Tasmania) make it unlawful to drive with any THC in your system, even if prescribed for medicinal purposes. In Tasmania, prescribed THC does not constitute an offence. Victoria allows magistrates to exercise discretion when THC is prescribed, but it remains unlawful. Patients require clear counselling about the legal implications of driving and that drivers can remain impaired for a variable and unpredictable period post-dose.

Clinical issues to consider

Drug interactions: Medicinal cannabis can affect the levels or effects of antiepileptics, benzodiazepines, methadone, and warfarin. Experts recommend caution and drug monitoring where appropriate.

Contraindications: Experts recommend against the use of medicinal cannabis in pregnancy, breastfeeding, children (except for approved CBD products for rare severe childhood epilepsies), or people at risk of psychosis.

Proceed with caution: If you choose to prescribe medicinal cannabis, you should ensure patients are**comprehensively assessed** (including medication, mental health and substance use history). **Document** why conventional treatments are inadequate. Obtain **informed consent** that explicitly addresses the off-label nature of prescribing, limited evidence base, potential risks, costs, and driving implications. Establish clear, measurable **treatment goals** before initiating therapy. Begin with **low doses** and titrate **gradually** whilst monitoring closely. If you are a specialist prescriber, communicate with the patient's regular GP about the treatment plan. Prescribe the smallest quantity consistent with therapeutic need. Maintain detailed **records** justifying every clinical decision. Be mindful of the Board's position on asynchronous telehealth, that is, it is not good practice and not supported by the Board.

Other common pitfalls

MIPS has observed a concerning rise in claims and complaints related to medicinal cannabis prescribing, particularly in vertically

integrated telehealth settings. Common issues include over-prescribing, prescriptions with no or minimal directions for use, prescribing to patients already on benzodiazepines, pregabalin, or opioids without proper assessment of interactions, and failure to check real-time prescription monitoring, where required. Vertically integrated telehealth companies that control advertising, prescribing, dispensing, and product supply create conflicts of interest and there is concern from regulators that they create demand among vulnerable patient cohorts.

Your prescribing checklist

Before prescribing medicinal cannabis, you need:

✓ To thoroughly assess the patient, obtain informed consent and only consider medicinal cannabis when clinically justified

✓ TGA approval for any unapproved medicinal cannabis products via the Authorised Prescriber Scheme or Special Access Scheme

✓ Comply with requirements for Schedule 8 prescribing in your jurisdiction (and/or that of the patient and dispensing pharmacy)

✓ Confirmation you have checked real-time prescription monitoring, where required

✓ To document your conversations with the patient and your clinical decisions in the medical record.

The bottom line

Medicinal cannabis prescribing requires careful navigation of regulatory requirements, robust clinical processes, and sound professional judgement. With claims and complaints increasing, particularly in the context of telehealth, staying informed and maintaining rigorous standards is not just good practice; it is essential protection.

By maintaining focus on quality patient care whilst understanding the regulatory and medico-legal context, practitioners can fulfil their professional obligations with confidence and competence.

Deepen your understanding

Ready to explore medicinal cannabis prescribing complexities in greater detail? Our comprehensive on-demand webinar and CPD offerings examine the regulatory landscape, risk areas, and practical strategies for safe, compliant practice.

Access our webinar: "Medicinal Cannabis Prescribing: Risk Areas and Regulatory Considerations"

Available now for MIPS members. Understanding these complexities protects both your patients and your professional practice.

For specific guidance on your prescribing obligations, consult your state/territory drugs and poisons authority and the TGA. Contact MIPS to discuss indemnity coverage for your specific practice circumstances.
