



Medicinal Cannabis: Quick guide for health professionals

- **Cannabis-Based Products (CBPs) in pharmaceutical forms are legal to prescribe and dispense in WA.**
- **Prescribing of CPB as Schedule 8 (S8) medicines (controlled drugs) requires approval from the WA Department of Health.**
- **Medicines that are not registered therapeutic goods require approval of the Therapeutic Goods Administration (TGA).**

Legal status

Nationally, CBPs are classified as S8, controlled drugs. CBPs in S8 can be legally supplied under normal rules for [prescribing and dispensing](#) of these medicines.

CBPs that contain less than 2% THC (as a percentage of the total cannabinoid content) are classified as Schedule 4 (prescription only) substances. These can be prescribed and dispensed as regular prescription medicines.

Efficacy

While there is some scientific literature that supports the use of CBPs in selected conditions, the evidence is limited, and of variable quality. The quantity of published research is expanding rapidly, and to date there is:

- moderate-quality evidence to support the use of CBPs in the treatment of chronic pain and spasticity
- low-quality evidence for the use of CBPs in sleep disorders, nausea and vomiting due to chemotherapy, and weight gain in HIV infection
- low-quality evidence for the use of cannabidiol in seizure disorders.

Prescribing

Approval for the WA Department of Health is required to prescribe any CBP in S8. There are two pathways:

- Notification pathway - specialist prescribers, including TGA Authorised Prescribers, and those prescribing for patients entered in a HREC approved clinical trial can apply for a [class approval](#)
- Authorisation pathway - medical practitioners can [apply for treatment](#) of individual patients on the basis of other indications. General practitioners will require the support of a consultant.

For specialist prescribers, who are not TGA Authorised Prescribers or treating clinical trial patients, the notification pathway is currently limited to treatment of multiple sclerosis, but is likely to be expanded as evidence accumulates for efficacy in other conditions. A specialist can appoint a General practitioner as a co-prescriber.

For other indications, requests for authorisation will be assessed in relation to any major safety concerns in individual cases, such as significant past history of psychosis or substance abuse disorder. It is expected that applications will usually originate from specialists. A General Practitioner may be authorised, however specialist support and supervision is necessary.

CBPs are not recommended as first line treatment for any condition at the present time – and should only be considered where alternative options are either ineffective or unsuitable. Practitioners should be aware of the limitations of current evidence surrounding the short and long term efficacy and safety of treatment. CBPs are not registered medicines and clinicians should be mindful that only basic quality standards are currently being applied. It is strongly recommended that potential risks are fully discussed with patients and written consent obtained.

Safety

Common short term adverse events include dizziness, dry mouth, nausea, fatigue, disorientation, and hallucination.

A recent systematic review and meta-analysis into CBPs for medical use found that there are no studies evaluating the long-term side-effects, even when searches were extended to include lower-levels of evidence.

Quality

Almost no CBPs are registered medicines in Australia. This means that individual products have not undergone formal assessment of efficacy, safety or quality through a recognised Australian regulatory authority.

The supply of unregistered medicines is regulated by the TGA. To prescribe a CBP, a medical practitioner must obtain approval from the TGA under the [Special Access Scheme](#) or the [Authorised Prescriber Pathway](#).

CBPs that are legally manufactured in Australia or imported under approval must meet basic [product standards](#). These standards are not completely equivalent to those normally required of prescription medicines.

Product availability

There are now a number of licensed CBP manufacturers and sponsors approved to import CBPs. Unregistered S8 medicines cannot be advertised or promoted, but interested practitioners can contact [approved suppliers](#) directly for more information. Suppliers must be licensed medicines wholesalers and are only able to supply to authorised health practitioners, such as doctors, pharmacists or hospitals.

There are numerous products and formulations available. The most appropriate for any particular indication or patient is a matter for individual clinicians to determine. Practitioners should seek information on the content, characteristics, dosing and other clinical considerations for CBPs from suppliers themselves.

Dispensing

A patient can present an approved prescription to any WA pharmacy for dispensing. Pharmacies can obtain products from licensed manufacturers or approved sponsors acting as pharmaceutical wholesalers (see product availability above). Pharmacies are required to store CBPs and maintain supply records in the same way as other S8 medicines.

Funding

CBPs are not funded as Pharmaceutical Benefits Scheme items. Prescribers should seek pricing information on specific products from suppliers and pharmacies.

Cannabis Based Products at a Glance

- CBPs are classified as Schedule 8 (S8) items (controlled drugs).
- Products containing cannabidiol only are Schedule 4 (prescription only) items.
- The prescribing of S8 CBPs requires the approval to the WA Department of Health.
- An authorised prescriber pathway is available to Specialists for limited indications and for medical practitioners treating patients in clinical trials.
- Other indications require approval for use in a particular patient.
- Most CBPs are not registered therapeutic goods.
- Supply of unregistered therapeutic goods requires the authorisation or approval of the TGA.
- CBPs can be dispensed by any WA pharmacy.
- Products are available from licensed manufacturers or approved sponsors.

Medicinal Cannabis: Case examples for health professionals

1. I want to prescribe nabiximols (Sativex®) for my patient's pain

Nabiximols is approximately 50:50 THC:CBD. As it is more than 2% THC, it is a Schedule 8 medicine, and will need application to the WA DoH. Sativex® is a registered medicine in Australia, so does not need TGA approval. Use for treatment of pain is an off-label indication.

2. I would like to prescribe dronabinol (Marinol®) for appetite stimulation

Dronabinol is more than 10% THC and classified as a Schedule 8 item. Prescribing will need the approval of the WA DoH. As it is not a registered good in Australia it will also need approval from the TGA.

3. I would like to use nabiximols (Sativex®) to manage Multiple Sclerosis

Nabiximols is approximately 50/50 THC:CBD and is a Schedule 8 item. For the indication of Multiple Sclerosis, neurologists can apply to be an authorised prescriber for this class of patient. Once authorised, the prescriber need only notify the DoH when each patient commences treatment. Sativex® is registered in Australia for this indication and does not need further TGA approval.

4. Can I prescribe Epidiolex® for my patient's epilepsy

Epidiolex® is more than 98% CBD and because it contains less than 2% THC, as part of the total cannabinoid content, is classified as a Schedule 4 item. There is no DoH approval required to prescribe a Schedule 4 medicine. As Epidiolex® is an unregistered good on the ARTG, it will need approval from the TGA to prescribe.

5. I know a local (legal) importer of cannabis oil and I want to use this for symptom control in palliative care

If the product contains more than 2% THC, as part of the total cannabinoid content, then DoH approval to prescribe will be required. An application to the DoH for individual patient authorisation will need to be made and receive approval. As this product is not a registered medicine, application for authorisation to prescribe must also be made to the TGA.

More information

Website: search 'medicinal cannabis' on the WA Health website at health.wa.gov.au

Email: MPRB@health.wa.gov.au

Office of Drug Control: odc.gov.au

Therapeutics Goods Association: tga.gov.au

Australian Government Legislation: legislation.gov.au

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