



Australian Government

Department of Health

Therapeutic Goods Administration

Medicinal cannabis products

Patient information

Over the past few years there has been increased interest from Australians in the use of cannabis for medicinal purposes. Commonwealth, state and territory governments have used existing laws or passed specific laws to allow the prescribing and dispensing of medicinal cannabis products, as well as cannabis cultivation and manufacture for medicinal purposes.

The evidence

There have been very few well-designed clinical trials using medicinal cannabis, so there is limited evidence on its success in treating different medical conditions, or on effective forms and dosages.

The studies that have been undertaken have focused mainly on the following five areas.

Epilepsy in children and adult patients

Evidence supporting the use of medicinal cannabis in the treatment of certain childhood epilepsies is strongest. Where the use of several anti-epileptic drugs has not helped their condition, the cannabis compound cannabidiol has been used (as an add-on to current treatments) in drug-resistant epilepsy in children and young adults up to 25 years. Several studies have reported improved quality of life in paediatric and adult groups, but overall there are few studies of how effective cannabidiol is in treating adult epilepsy.

Multiple sclerosis (MS)

Nabiximols, a cannabis plant extract, is registered with the TGA for use in muscle spasticity associated with MS, but is not listed on the PBS. Five studies out of ten carried out on other cannabinoids concluded that cannabinoids may be effective for symptoms of pain and/or spasticity and may have a positive effect on sleep and bladder symptoms. The other five studies were inconclusive or did not show that treatment with cannabinoids had any positive effect in MS.

Chronic non-cancer pain

Most of the studies on chronic non-cancer pain involved using medicinal cannabis in addition to other pain medications, and focused on chronic (long-term) rather than acute (short-term) pain.

There is some evidence that cannabinoids can reduce pain in neuropathic pain, but for many people the reduction in pain may be small.

There is not enough information to tell whether medicinal cannabis is effective in treating pain associated with arthritis and fibromyalgia.

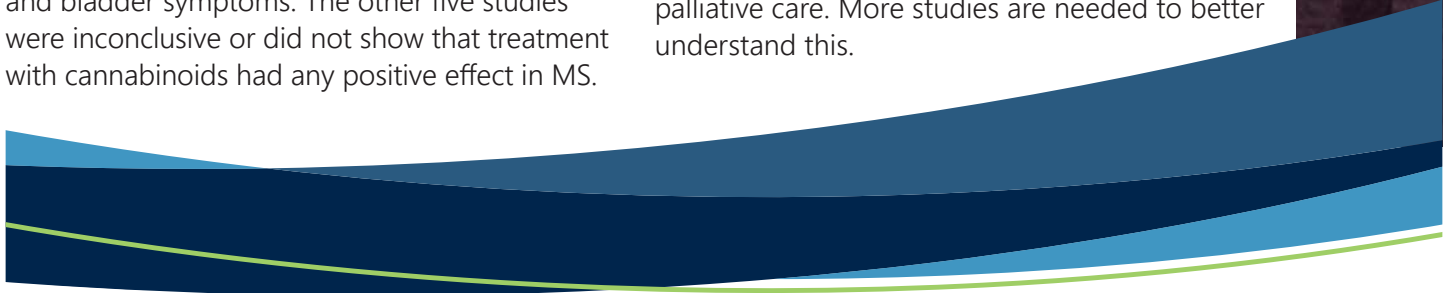
Chemotherapy-induced nausea and vomiting in cancer (CINV)

Only a small number of studies showed relief from symptoms of CINV in patients using medicinal cannabis and the quality of published evidence is low to moderate. These studies were also compared against now-outdated treatment options, rather than against current standards of care.

Medicinal cannabis should only be prescribed for CINV if other options have failed.

Palliative care

There are very few studies on medicinal cannabis treatment in palliative care, so it should be used only after standard treatments have failed. Medicinal cannabis may interact with chemotherapy and other medications used in palliative care. More studies are needed to better understand this.



Access to medicinal cannabis

With the exception of one product (Nabiximols), medicinal cannabis products are not registered medicines in Australia, and none are subsidised through the Pharmaceutical Benefits Scheme (PBS), so they can only be accessed through special pathways available for unapproved medicines.

A variety of products are currently available through these pathways, via import from Canada or Europe. These include raw (botanical) cannabis which may be vaporised for medicinal purposes, as well as oils, liquids and oral sprays. Some products have also been developed for direct application to the skin (gels).

Similar products made from locally grown medicinal cannabis are expected to become available during 2018.

Medicinal cannabis **can only be prescribed by a registered medical practitioner** after a thorough assessment to decide if the treatment is appropriate for the patient's condition and individual circumstances.

If a doctor decides that a medicinal cannabis product is suitable for the patient, they must apply for approval to prescribe it under the applicable state or territory laws. Rules relating to medicinal cannabis products vary between states and territories and could affect whether or not medicinal cannabis can be prescribed.

Individual patients cannot apply to the TGA for access to medicinal cannabis products.

Side effects

Like all prescription medicines, medicinal cannabis products can have side effects. These may include:

- fatigue and sedation
- vertigo
- nausea and vomiting
- fever
- appetite increase or decrease
- dry mouth
- diarrhea
- convulsions
- feelings of euphoria (intense happiness) or depression
- confusion
- hallucinations or paranoid delusions
- psychosis or cognitive distortion (having untrue thoughts)

The extent of side effects can vary with the type of medicinal cannabis product and between individuals.

Cautions

Patients using any medicinal cannabis products should seek their doctor's advice before driving or operating machinery due to the risk of experiencing drowsiness. While drowsiness is not a known side effect of CBD alone, it may occur if the CBD interacts with other medications. Some medicinal cannabis products may also include tetrahydrocannabinol (THC), in which case there is a strict ban on driving and operating machinery.

Patients with conditions of the nervous system may be more likely to experience negative effects from medicinal cannabis.

Although medicinal cannabis treatment may help one condition or symptom, this does not mean it will have benefits for other conditions or individuals, even with the same product and the same dose.

There is also very limited evidence about how medicinal cannabis reacts with other approved medications.

More research is needed

There is a significant need for larger, high-quality studies to explore the potential benefits, limitations and safety issues associated with medicinal cannabis treatment across a range of health conditions and symptoms.

If more studies support medicinal cannabis use and provide evidence for particular forms, dosages and administration methods, it is more likely that doctors will feel confident in prescribing medicinal cannabis over other approved options.

Further research will also compare medicinal cannabis with standard medication options and build knowledge on how medicinal cannabis interacts with other drug treatments.



For more resources and further information about medicinal cannabis go to the TGA Website <https://www.tga.gov.au>