



Guidance for the use of medicinal cannabis in Australia: Patient information

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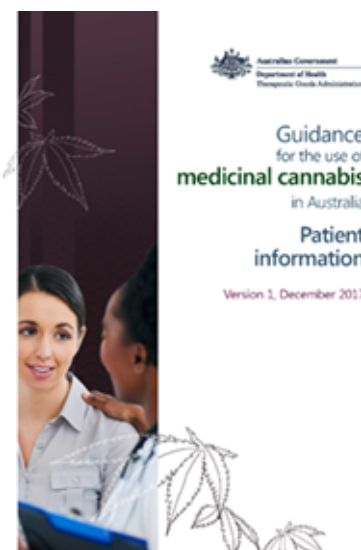
Medicinal cannabis: patient information

Over the past few years, a number of Australians have expressed interest in the use of cannabis for medicinal purposes. The Commonwealth and State and Territory governments have either used their current laws or passed specific laws to allow the prescribing and dispensing of medicinal cannabis products. The Commonwealth, and in some cases, State and Territory governments, have also passed laws allowing cannabis cultivation and manufacture for medicinal purposes.

Currently there is limited evidence about the effectiveness of medicinal cannabis for use in different medical conditions. There is also little known about the most suitable doses of individual cannabis products.

This is why, with the exception of one product (nabiximols), medicinal cannabis products are not registered on the Australian Register of Therapeutic Goods (ARTG) and, in like most other countries, are not available as registered prescription medicines.

For a particular product to be registered on the ARTG, a sponsor (usually a company) would need to submit a dossier of evidence on the clinical efficacy, safety and manufacturing quality of a particular medicinal cannabis product to the Therapeutic Goods Administration. At this time, the Australian Government does not subsidise the cost of medicinal cannabis products through the



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Pharmaceutical Benefits Scheme (PBS).

The Australian Government Department of Health and the NSW, Victorian and Queensland state governments commissioned a team from the Universities of New South Wales, Sydney and Queensland under the co-ordination of the National Drug and Alcohol Research Centre (NDARC) to review the available clinical evidence for using medicinal cannabis. The team focused on the five areas for which the largest numbers of studies have been carried out - palliative care, chemotherapy-induced nausea and vomiting, chronic pain, multiple sclerosis and epilepsy in paediatric and adult patients.

The researchers conducted a review of previously published reviews from multiple databases such as Medline, Embase, PsychINFO and EBM Reviews. Searches were guided by a specialist Librarian using specific search terms and were limited to studies published between 1980 and early 2017. Two reviewers independently examined titles and abstracts for relevance and the GRADE (grading of recommendations, assessment, development and evaluation) approach to evaluating the quality of evidence was also applied. The GRADE^[1] method is the international standard that applies to weighting of evidence in scientific and medical literature and gives weight to certain evidence based on the level of evidence and strength of recommendation. For example, evidence as a result of randomised control trials (RCTs) are given priority because this study method typically yields more reliable results. RCTs are at the top of the hierarchy of evidence.

This brochure provides a broad overview of the current evidence to support using medicinal cannabis for the above conditions. It also highlights the cautions surrounding treatment, how medicinal cannabis can be prescribed and future research.

The Department of Health will update this brochure as new evidence emerges.

1. Johansen and Thomsen 2016, *Review Article* - Guidelines for Reporting Medical Research: A Critical Appraisal, International Scholarly Research Notices, article ID1346026

The evidence

Doctors rely on evidence to make informed decisions about the best medications for their patients. For medicinal cannabis, the amount of evidence is currently limited and the products, doses and research methods used vary between studies. This makes it difficult to come to firm conclusions about how best to use particular medicinal cannabis products.

There is also not much information available to help doctors determine the most appropriate and safe doses while minimising potential side-effects. Importantly, at the moment, relatively few studies compare the effects of medicinal cannabis products against currently approved treatments for various conditions and symptoms. In addition, most of the studies reported in the medical literature have either used purified pharmaceutical substances or smoked cannabis.

As there is limited scientific evidence to support the use of medicinal cannabis in most conditions, and in many cases the evidence is for its use together with other medicines, it should be used only when approved treatments have been tried and have failed to manage conditions and symptoms.

Access to medicinal cannabis

Medicinal cannabis can only be prescribed by a registered medical practitioner.

Before prescribing medicinal cannabis, the doctor will assess each patient to decide if the treatment is appropriate for their condition and individual circumstances. The doctor will take a medical history and a family health history. The doctor will also consider the patient's current medications and any problems with drug dependence and substance abuse.

With the exception of one product (nabiximols), medicinal cannabis products are not registered medicines in Australia, so they must be accessed through special pathways available for unapproved medicines.

Individual consumers cannot apply to TGA to obtain approval to access unapproved medicinal cannabis products. Such access can only be arranged through an Australian-registered medical practitioner with appropriate qualifications and/or expertise for the medical condition requiring treatment. This doctor can notify/apply on the patient's behalf for approval to import and supply these products through the Special Access Scheme (SAS Category A or B). Alternatively, the doctor can apply to us to become an Authorised Prescriber (AP). Approval or authorisation is granted on a case-by-case basis.

This doctor must also apply and obtain approval under the applicable state or territory laws to prescribe a medicinal cannabis product to a particular patient, where relevant. Rules relating to medicinal cannabis products vary between states and territories and could affect whether or not you can be prescribed particular medicines in your state or territory.

If both state and TGA requirements are satisfied then the pharmacy or hospital that the doctor has arranged to supply the product can dispense it. The medicinal cannabis products may already be available in Australia if the Office of Drug Control has authorised their import. The [Office of Drug Control website](#) gives a list of companies who have been authorised to import medicinal cannabis stock into Australia for supply through SAS approvals or AP authorisation. Please note that inclusion on this list does not guarantee stock availability or automatic approval for patient access by the TGA or the states and territories.

Should the product requested not be authorised to be held in Australia then the doctor (or pharmacist/hospital on the doctor's behalf) wishing to import the product may then need to obtain import permits from the Office of Drug Control.

The products

A variety of products are currently available through import from Canada or Europe. These include raw (botanical) cannabis, which for medicinal purposes should be vaporised but not smoked, cannabis extracts in oils, and solvent extracts such as tinctures, and oro-mucosal sprays. Some products for trans-dermal application (patches or topical application of gel or cream) have also been developed.

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

A challenge is that many of the studies described in the medical literature have used either smoked cannabis (which is not recommended on health grounds) or purified tetrahydrocannabinol (THC) or cannabidiol (CBD), rather than many of the types of products that are currently available internationally.

There are up to 100 cannabinoids in the cannabis plant. The cannabinoids are most abundant in the female flower head, which is used in the manufacture of medicinal cannabis products.

Tetrahydrocannabinol (THC) is responsible for the psychoactive effects of cannabis and is the reason cannabis is used recreationally. THC may also be responsible for some of the medicinal effects of cannabis such as reduction of nausea, vomiting, pain and muscle spasms as well as improvements in sleep and appetite.

A second cannabinoid, cannabidiol (CBD) is not psychoactive and may be useful in the management of seizures, pain, and may have anxiolytic and antipsychotic effects. Different

cannabis strains contain different ratios of THC to CBD. It is unclear whether THC and CBD act individually or synergistically (in conjunction with each other). Other cannabinoids under active research include cannabigerol (CBG), tetrahydrocannabivarin (THCV), cannabinol (CBN) and cannabichromene (CBC). The cannabis plant also contains terpenes which give cannabis its flavour and aroma. It is unclear whether terpenes have their own pharmacological effects.

Medicinal cannabis and epilepsy in paediatric and adult patients

The main purpose of epilepsy medications is to reduce the number of seizures and ideally to stop them altogether. There is some evidence to support using medicinal cannabis in the treatment of certain childhood epilepsies.

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Cannabidiol (CBD) is the substance featured in most published evidence on medicinal cannabis as an epilepsy treatment.

However, this evidence is when it is used as an add-on to current treatments in drug-resistant epilepsy in children and young adults up to 25 years where use of several anti-epileptic drugs has not controlled their condition. In patients with paediatric-onset drug-resistant epilepsy, CBD products reduced seizure frequency by 50 per cent or more in up to half of the patients and achieved seizure freedom in a small number of patients. Several studies have reported improved quality of life in paediatric and adult groups, but overall there are few studies of how effective CBD is in treating adult epilepsy. There is not enough evidence to recommend this treatment for adults.

There is no evidence to support medicinal cannabis as a rescue therapy for status epilepticus (a single seizure lasting more than five minutes or two or more seizures within a five-minute period without the person returning to normal between episodes).

Information is limited on the most effective starting doses to treat epilepsy in children and young adults. As extra care is needed, it is expected that paediatric neurologists would be involved in the management of these children.

Medicinal cannabis and multiple sclerosis (MS)

There is a TGA registered medicine (Nabiximols, which are an extract of cannabis plant

containing roughly equal amounts of THC and CBD) for the use in MS for muscle spasticity. Five of ten studies carried out on other cannabinoids concluded that there was evidence that cannabinoids may be effective for symptoms of pain and/or spasticity and positive effects on sleep and bladder symptoms. It should be noted that the other five studies were inconclusive or did not show that treatment with cannabinoids had any positive effect in MS.

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There is some low to moderate evidence to suggest that medicinal cannabis products may be effective for treating the pain symptoms of MS, although this is inconsistent. Studies differ as to whether medicinal cannabis products can help improve bladder function, sleep, quality of life, ataxia/tremor and disability/disease progression.

There are also currently no studies that compare medicinal cannabis products to the most effective and commonly-used medications for MS pain and spasticity. Therefore, there is no evidence to support the use of most cannabinoids as a single, primary or initial treatment.

Treating doctors should assess people with MS after 12 weeks to re-evaluate and monitor both the positive and negative effects of the drug.

Treating chronic non-cancer pain

The majority of the studies on the use of cannabinoids in pain have studied THC or THC-rich extracts. The studies are mainly where cannabinoids were "adjuvant" treatments, used in addition to other pain medicines.

Most studies have been on chronic (long-term) rather than acute (short-term) pain. Patients and healthcare professionals recognise that there are two main types of chronic pain. Nociceptive pain, which can be found with or without cancer, is caused by damage to body tissue and usually described as a sharp, aching, or throbbing pain to the bones, muscles, or joints, or that causes the blockage of an organ or blood vessels. Neuropathic pain occurs when there is nerve damage, in particular to those nerves in the spinal cord. The pain is often described as a burning or heavy

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sensation, or numbness along the path of the affected nerve.

There is some evidence that cannabinoids can reduce pain in both MS related neuropathic pain and non-MS related neuropathic pain, but for many people the reduction in pain may be modest. There is, however, insufficient information to make a conclusion about cannabinoids for the treatment of pain associated with arthritis and fibromyalgia.

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Current studies show no evidence that medicinal cannabis can improve overall quality of life or physical functioning. There is also some evidence that it can improve sleep.

There is much interest at present as to whether cannabinoids are "opioid sparing" – in other words, whether use of medicinal cannabis products for pain can result in a reduction of use of strong opioids. If this were the case, deaths and incapacity from opioid overdoses could be reduced, given that cannabinoids have fewer adverse outcomes. While some individuals with pain have reported that their use of opioids has been reduced when they also use medicinal cannabis, clinical studies in this area are still ongoing.

Preventing and managing chemotherapy-induced nausea and vomiting in cancer (CINV)

There are some reports that medicinal cannabis products (in particular THC and related substances) relieved the symptoms of CINV. However, the number of studies is small and the quality of published evidence is low to moderate. While several studies found that the medicinal cannabis products were as effective as the prescription medicine it was compared with, most of the research studies were carried out some years ago, and in recent years much more effective prescription medicines for nausea and vomiting have become available.

For these reasons, THC-rich medicinal cannabis products for chemotherapy induced nausea and vomiting should be prescribed only after standard approved treatments have failed.

Medicinal cannabis use in palliative care

While medicinal cannabis products can be used to treat nausea and vomiting due to chemotherapy, there is little evidence of any

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