CanGuide
Navigating Medical Cannabis

FACT SHEET:
MEDICINAL CANNABIS

In November 2016, medicinal cannabis was reclassified, making it a legal treatment option in Australia for healthcare practitioners to prescribe under special circumstances.

What is medicinal cannabis?

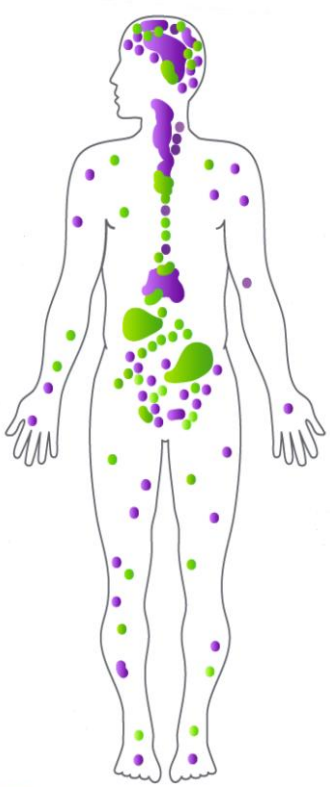
Medicinal Cannabis is a pharmaceutical grade cannabinoid-based medicine prescribed for the management of a medical condition, usually where standard treatment options have failed.

What is the endocannabinoid system?

The human endocannabinoid system is a system within our bodies that produces and uses endocannabinoids. It is a biochemical control system involved in regulating numerous bodily processes and includes both endocannabinoid and cannabinoid receptors [1,3,4].

> *Endocannabinoids and their receptors are found throughout the body: in the brain, organs, connective tissue, glands and immune cells. In each tissue, the cannabinoid system performs different tasks, but the goal is always the same: homeostasis, the maintenance of a stable internal environment despite fluctuations in the external environment.* [5]
> Dr Dustin Sulak

CB1 and CB2 receptor function is to receive chemical signals to control cellular activity and play an important role in signal processing in the brain [5]. Cannabinoids have also been found to have effects outside the CB1/CB2 receptor system [1] and studies are attempting to identify other potential receptors.



CB1

CB1 Receptors are abundant in the central nervous system, particularly in the cortex, basal ganglia, hippocampus, and cerebellum of the brain [6,8]; however, they are sparse within the brainstem [9].

CB2

CB2 Receptors are abundant throughout the body however are present in much lower levels compared to CB1 receptors in the brain [6,8].

The endocannabinoid system has been recognised as an important system in the function of the brain, endocrine and immune tissues. It functions to contribute to keeping the internal processes of the body's cells and organs stable. It appears to play a very important regulatory role in the secretion of hormones related to reproductive functions and response to stress, giving these endocannabinoids wide-ranging effects on everything from fertility to pain.

Cannabinoid receptors can be found in the brain, nervous system, gastrointestinal tract, bone, immune system, skin and nearly every other organ in the body. Experts are still trying to fully understand the endocannabinoid system but so far, we know it plays a role in regulating a range of functions and processes including:

- Appetite
- Bone health
- Fertility
- Immune function
- Inflammation
- Mood
- Memory
- Pain sensation
- Skin health
- Sleep
- Stress response

What are cannabinoids?

The human body has an endocannabinoid system where chemical compounds called endocannabinoids interact with receptors in the body to maintain different functions of the body. However, the human body is not the only way cannabinoids can be produced.

Cannabinoids can be produced in one of three ways:

1. Naturally within the human body. These are called endocannabinoids because 'endo' means 'within'
2. Naturally from plants. These are called phytocannabinoids because 'phyto' means ' coming from a plant'
3. Synthetically which include human-made chemicals produced to mimic the effect of phytocannabinoids

For some people, the endocannabinoid system does not work at its optimal level. At these times, or in the case of some illnesses or diseases, the endocannabinoid system may benefit from cannabinoids from external sources.

How does medicinal cannabis work?

The cannabis plant consists of more than 140 phytocannabinoids and over 400 trace compounds, including terpenes, flavonoids, and omega-3 and 6 fatty acids [2], which work together and can be found in various ratios in the differing strains of the plant.

The main active ingredients of cannabis used for medical purposes are tetrahydrocannabinol (THC) and cannabidiol (CBD). However, other compounds of interest, CBDA, CBDV, THCA, CBG, CBGA, CBN, and CBC are the focus of studies for medical purposes.

THC is the psychoactive part of cannabis that produces a 'high' and has been used to treat symptoms such as nausea, pain and muscle spasticity.

CBD has no psychoactive properties and has been used to treat several inflammatory disorders and seizures in certain epilepsies [10].

At present the evidence base for the use of medical cannabis products is limited and varied between different medical conditions. Recent reviews and analyses indicate there may be some therapeutic benefits of medical cannabis products in certain conditions; however, further research on the treatment effectiveness and longer-term side effects is necessary and ongoing.

Can my GP prescribe medicinal cannabis?

There are currently two medicinal cannabis products registered for use in Australia for the management of spasticity in people with multiple sclerosis and the management of seizures in people with Dravet and Lennox-Gastaut Syndrome, which are rare, severe forms of epilepsy.

Doctors can access medicines not yet approved for listing on the Australian Register of Therapeutic Goods (ARTG), which are also referred to as 'unapproved' medicines. There are a number of TGA pathways a doctor can access 'unapproved' medicines for their patients

- Authorised Prescriber Scheme [AP],
- Special Access Scheme [SAS], or
- Clinical trials

The prescriber will need to apply to the TGA for approval to prescribe medicinal cannabis before writing the prescription. The approval and prescription are then submitted to a pharmacist for supply.

The requirements for prescribing medicinal cannabis for children under 18 years have changed, and the prescriber will need to review the updated regulations in the TGA Medicinal Cannabis Hub.

The cost of accessing medicinal cannabis products not yet listed on the ARTG or PBS varies depending on the formulation of medication and dose required, and the patient is responsible for all costs associated with this access. Some Health Funds provide a rebate for medical cannabis, contact your health fund for more information. Some medical cannabis pharmaceutical companies offer compassionate access programs; the companies are not permitted to speak directly with patients, so ask your prescribing doctor to make contact. In several states and territories, patients may be eligible for government-funded medical cannabis compassionate use schemes.

What types of medicinal cannabis products are available?

Medicinal cannabis products are available in different forms, such as oils, capsules, wafers, lozenges, oro-mucosal sprays, tinctures, dried flowers, and other forms for inhalation.

What are the side effects of medical cannabis treatment?

Like all prescription medicines, medical cannabis products can have side effects. The extent of these can vary with the type and dose of the medicinal cannabis product, and between individuals.

In general, the side effects of CBD-rich products are less than those for high-THC products, but because the required doses for CBD can be quite high in conditions such as paediatric epilepsies, a proportion of patients encounter side-effects with these high CBD doses.

The known side-effects from medicinal cannabis treatment, CBD and THC, include fatigue and sedation, vertigo, nausea and vomiting, fever, decreased or increased appetite, dry mouth, and diarrhea.

THC products, especially products high in THC have been associated with seizures, feeling high or feeling dissatisfied, depression, confusion, hallucinations, paranoid delusions, psychosis, and cognitive distortion (an altered interpretation of reality).

How is the dosage decided?

There is a growing body of information on the most effective and safe doses for various conditions and symptoms. Starting doses should be low and increased over time until patients respond positively, or negative effects outweigh the perceived benefits. Low start doses are particularly important for people with memory and thinking difficulties, liver and kidney disease, and weakness and wasting of the body due to severe chronic illness. Low start doses are also important for young people and the elderly.

Generally, people with epilepsy require a much higher dose than people with other conditions.

What are the general precautions for treatment with medicinal cannabis?

People should not drive or operate machinery while being treated with medicinal cannabis containing THC. Measurable concentrations of THC can be detected in urine many days after the last dose. Drug driving is a criminal offence, and patients should discuss the implications of safe and legal driving with their doctor.

Medicinal cannabis is not considered appropriate for:

- People with unstable cardiovascular disease
- Women who are pregnant, planning to become pregnant or breastfeeding
- People with an active or previous psychotic disorder, or concurrent active mood or anxiety disorder.

There is very limited evidence to show how medical cannabis reacts with other medications, however, cannabinoids, specifically cannabidiol [CBD] can compete with other medications in the liver to be metabolised [9,12].

It is important to be aware of this potential effect and discuss this with your prescribing doctor to guide you in monitoring and adjusting your treatment regime when considering or commencing cannabinoid products.

Summary

For some people with certain medical conditions, the use of prescribed medical cannabis can significantly enhance their quality of life; for others, it may have little to no effect. Although the number of research studies has significantly increased over the past 10 years, more research is needed to increase the body of evidence that will give both doctors and patients vital information to assist in the prescribing and use of precision cannabinoid-based medicines. Doctors and their patients need to be in an open discussion about the potential use of medicinal cannabis for their individual health conditions and circumstances.

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