# **GET THE FACTS**

# Medicinal cannabis regulation changes: giving faster access to terminally ill patients

The Australian Greens have led the way so that patients with life threatening illnesses will now have faster access to medicinal cannabis prescribed by their doctor.

We know there is a lot of information flying around – not all of it accurate – about this change, so we've compiled this FAQ to help you get to bottom of it.

There is strong evidence showing benefits for patients with, for example, life threatening cancers who suffer nausea as a result of their chemotherapy.

For patients, getting access to medicinal cannabis at the earliest possible opportunity means the difference between suffering severe seizures, vomiting, and excruciating pain, and having some level of relief.

#### **ACCESSING MEDICINAL CANNABIS**

## Will access to medicinal cannabis be widened in Australia?

The Greens strongly support reforms that would enable patients to access the medicine they need, including medicinal cannabis. It's over 18 months since the government introduced legislation to make medicinal cannabis legal in Australia – and yet patients are still waiting for access.

The Greens are continuing to work with patients, the medical profession, the community and government to make this a reality.

#### How can I access medicinal cannabis?

If you believe medicinal cannabis may be helpful for your own condition speak to your doctor about treatment options.

As there is not yet an Australian medicinal cannabis supply your doctor will need to prescribe it through the Special Access Scheme (see below). Our win in the Senate means if you meet the definition for category A – they will be able to prescribe it straight away.

You can also access medicinal cannabis through 'authorised prescribers' although there are only 25 in the country altogether, none are General Practitioners, and they are unable to advertise – so it's very hard to find them!

United in Compassion is a great source of advice and information about access medicinal cannabis – a good place to start is their website here: **unitedincompassion.com.au** 

#### **ABOUT MEDICINAL CANNABIS**

#### What are the benefits of medicinal cannabis?

There is substantial evidence to support the use of medicinal cannabis in treating pain and nausea associated with some chemotherapy treatment, cancer, brain tumours and seizures resulting from intractable epilepsy.

For these patients access to medicinal cannabis at the earliest possible opportunity means the difference between suffering severe seizures, vomiting, and excruciating pain, and having some level of relief.

## What is the difference between cannabis and medicinal cannabis?

Cannabis or marijuana refers to the cannabis plant and raw plant material.

While medicinal cannabis is an approved, quality assured, cannabis derivative prescribed to treat symptoms of a medical condition or the side effects of treatment under qualified medical supervision.

Cannabis is a prohibited drug in Australia and the use of recreational cannabis or smoking cannabis for medical reasons remains prohibited.



"Overturning the government's harsh exemption of medicinal cannabis is a huge victory for patients and their families."

Dr Di Natale, Leader of the Australian Greens, has been a champion for drug law reform since entering parliament in 2010. As a GP, he understands the harsh reality of terminal illness and the role that medicinal marijuana can play in helping patients manage.

#### How is medicinal cannabis managed in Australia?

In Australia medicinal cannabis is regulated by the Therapeutic Goods Administration – the same agency with regulates all medicines.

The Special Access Scheme allows terminally ill patients to rapidly access medicines which aren't yet available in Australia.

The SAS of the TGA is designed to provide a pathway for Australian patients to access treatments that are not registered in Australia. It allows doctors to prescribe the most appropriate treatments to their patients even when that treatment is not readily available in our country.

There are two tiers, or categories, of the scheme – category A and category B – which have different levels of regulatory burden associated with them, dependent on the condition of the patient.

Category A are defined as: 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.

Category B is for any other patients who do not meet the very strict definition under category A.

If your doctor determines that you meet the definition for Category A, they can write you a prescription then and there for any medicine which is not yet available in Australia, which may provide you relief.

If your condition is not terminal, your doctor can make an application to the TGA and must approval from the TGA before they can give you a prescription.

This process is often lengthy and confusing - adding weeks or months to your wait for treatment.

#### What is the Special Access Scheme? Can I access it?

The Special Access Scheme allows any doctor to prescribe medicines which aren't yet available in Australia. You should speak to your doctors about the scheme and appropriate treatment options for your condition.

For more information on the Special Access Scheme, visit www. tga.gov.au/form/special-access-scheme

# I found medicinal cannabis products for sale Online. Are these products legal?

No. While there are a number of websites selling products which claim to be 'medicinal cannabis' products, only products prescribed by your doctor are safe, legal and can be accessed under the SAS.

#### ABOUT THE GREENS' LEGISLATIVE CHANGES TO IMPROVE ACCESS TO MEDICINAL CANNABIS

#### What regulation changed?

Last year, the government introduced a regulation so that medicinal cannabis was no longer available under the rapid access approval process (Category A). This cut off access for terminally ill patients and forced them to use the much slower Category B approval process. This made it much harder for terminally ill patients' access to medicinal cannabis prescribed by their doctor.

In response, the Greens led a vote in the Senate that overturned this government regulation. The Greens motion passed 40 votes to 30, with support from Labor, One Nation and independent senators Jacqui Lambie, Derryn Hinch, David Leyonhjelm and Lucy Gichuhi.

#### How will these regulation changes affect patients?

Effective immediately, terminally ill patients can now seek a prescription from their doctor straight away, without having to wait weeks or often months before their doctor can prescribe.

In addition, terminally III patients can now go overseas to more mature medicinal cannabis markets, like the US, or Canada and bring back a limited personal supply of this medicine for up to three months, making it quicker and easier for them to access the treatment they need.

But unfortunately there are still serious barriers to access at the state and territory level – in particular in relation to importing these products from overseas.

#### **ABOUT THE SAFEGUARDS**

# What safeguards are in place to stop someone accessing medicinal cannabis that doesn't need it?

Under the TGA's Special Access Scheme, a doctor is required to use their clinical judgment to determine that their patient meets the 'terminally ill' definition for category A. After any prescription is written under category A, the TGA is notified, and that decision can be audited by the regulator.

Doctors are also overseen by the Australian Health Practitioners Regulation Authority (AHPRA), a regulatory body that can investigate any element of clinical practice including these decisions.

