

# Medicinal cannabis use and public safety considerations

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## Use of cannabis and cannabis-derived products as medicines

The term medicinal cannabis describes a range of cannabis products used for therapeutic purposes. The cannabis plant contains hundreds of bioactive compounds, however there are two main active constituents used for medicinal purposes; delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Medicinal cannabis products are either plant derived or synthetically produced and vary in their concentrations of THC and CBD.

THC is responsible for the intoxicating effects of cannabis. In contrast, CBD is non-intoxicating.

In NSW cannabis medicines and cannabis products are regulated by the Australian Government and the NSW Government under various legislation:

- The Therapeutic Goods Administration (TGA) regulates patient access to cannabis medicines under the [Therapeutic Goods Act 1989](#)
- The NSW Ministry of Health regulates access under the *NSW Poisons and Therapeutics Goods Act*

Any doctor in NSW can prescribe a cannabis medicine for their patient.

[Cannabis medicines](#) are regulated similarly to other plant-derived medicines.

### Registered medicines

Two plant-derived medicines are listed on the Australian Register of Therapeutic Goods (ARTG), which means they have been assessed by the TGA for safety, quality and efficacy:

- Sativex® (nabiximols): a THC/CBD combination in a 1:1 ratio.
- Epidyolex® (cannabidiol) a CBD only product.

Epidyolex® has also been considered by the Pharmaceutical Benefits Advisory Committee and is available on the Pharmaceutical Benefits Scheme for relevant patients.

These medicines were able to be considered by the TGA for ARTG listing for use in Australia because there is enough evidence available to demonstrate that they meet requirements, including scientific trial information about how the drugs are likely to affect the body, and clinical trials demonstrating the effectiveness and side effects of the medicines for the specified conditions that they are registered for managing.

Generally, registered medicines have a:

- Product information monograph that provides information about the use and safety of the drug (predominantly written for health professionals), and
- Consumer medication information leaflet that provides consumers with relevant information about the medicine.

The product information and consumer medicine information also provide information about precautions users need to take when using the medicines – including considerations around driving or operating heavy machinery and interactions between medicines.

## Unregistered medicines

All other cannabis medicines are unregistered in Australia. Cannabis products that are unregistered, but are produced to a certain standard ([Therapeutic Goods Order 93](#)) are allowed to be sold (there are currently greater than 500 products available in this category in Australia). Unlike registered medicines, these products have not been evaluated by the TGA for safety, quality or efficacy.

This can present difficulties for prescribers, pharmacists and patients due to the lack of both product and consumer medication information.

Until recently, most unregistered medicines accessed in Australia were either those used in clinical trials overseas but not yet marketed in Australia, or those registered in overseas markets but not available in Australia. Unregistered medicines are accessed either through the Special Access Scheme, the Authorised Prescriber Scheme or through clinical trials.

The global growth of cannabis medicines and the large number of products available have led to some [concerns amongst regulators](#) that patient care may be compromised. This concern in part arises from the limited evidence base for the therapeutic use of cannabis, and that other treatments may be more appropriate for many patients. There are also concerns around costs to patients, particularly where there is vertical integration of marketing, prescribing, commercial supply of the medicines and dispensing. Because the medicines are unregistered they are not eligible for consideration for listing on the Pharmaceutical Benefits Scheme, meaning out of pocket expenses can be considerable. Concerns have been expressed by prescribing clinicians, including GPs and regulators around meeting the challenge of protecting the public from harm and inappropriate prescribing, whilst still allowing legitimate access to medicines.

The number of individuals prescribed cannabis medicines in NSW is not reliably known. In the past 12 months, more than 1.2 million Schedule 8 cannabis medicines were dispensed to people (not necessarily resident) in NSW. Schedule 8 medicines are subject to strict controls because of their high potential for harmful or hazardous use and dependence.

A key concern with unregistered medicines is advice around effects on complex tasks such as driving or operating heavy machinery. This is because products (particularly raw flower) may be used in different ways (e.g., smoked, vaporised, ingested as tea) and the product composition may vary from batch to batch (e.g., other components of the plant which may also have pharmacological effects). Whilst medical practitioners and pharmacists may have a general understanding of effects, it becomes more difficult to provide guidance to patients regarding likelihood of impairment, duration of impairment and THC levels relevant to individuals. General principles of managing medicinal cannabis and driving are described in the [Assessing Fitness to Drive for Commercial and Private Vehicle Drivers guideline](#).

## Illicit cannabis products

Beyond registered cannabis products used for therapeutic purposes, a substantial number of people in Australia choose to use illicit products for health symptoms, such as difficulty sleeping or pain. This may be due to the high cost of medical cannabis, which limits access for some individuals.

People using illicit cannabis will not have high quality information about potential impairment or medication interactions of specific products, as well as potentially having suboptimal diagnosis and therapy for their health condition.

According to the most recent [National Drug Strategy Household Survey](#):

- 7 in 10 people (70%) who used cannabis exclusively for medical purposes in the previous 12 months did so without a prescription
- 1 in 5 people (22%) had always had their cannabis for medical purposes prescribed by a doctor.

A 2021 study found people using illicit cannabis for therapeutic reasons were more likely to be using for the purpose of helping with sleep – other uses were similar to those using prescribed cannabis medicines (including pain, mental health/substance use disorders, neurological reasons and for cancer).<sup>1</sup> Those using illicit cannabis often cited difficulty navigating prescribed cannabis pathways as a barrier for use.

## Driving and cannabis medicines

THC can affect sensory, cognitive and motor skills necessary for safe driving, such as attention, judgement, memory, vision and coordination, possibly resulting in a crash causing death or injury. For more information see the NSW Health [Prescribed cannabis medicines and fitness to drive](#) document.

Roadside oral fluid testing is designed to deter driving after taking drugs and is conducted in all Australian jurisdictions, including NSW, where testing detects THC, MDMA, methamphetamine and cocaine. Roadside oral fluid screening devices are designed to detect recent use of these substances (typically within hours for THC based on current device technology).

These substances have been chosen due to their recognised impact on road crash fatalities. Crash data in NSW shows that between 2018 and 2022 there were 226 fatal crashes that involved drivers and riders with the presence of THC. This represents 16% of all fatal crashes in this period.

The evidence for prescribed cannabis medicines that contain THC and its relationship with crash fatalities and other road trauma is less clear. The NSW Government is committed to monitoring developments in the international and Australian research on this issue. In May 2024, the Victorian Government announced an 18-month [trial](#) to assess the effects of prescribed cannabis on people's driving on a closed-circuit track.

## NSW law and models in other jurisdictions

In NSW, it is unlawful to [drive impaired after exposure to any medicine](#). It is also an offence under the *Road Transport Act 2013* (NSW) to drive with certain defined substances including THC, cocaine, methamphetamine or MDMA 'present' in the driver's saliva, blood or urine. Evidence that the driver was impaired is not required for this offence to be proven, and most offences are detected through roadside screening tests and analysis of oral fluid. Drivers who screen positive to any of these defined substances have further sampling of their oral fluid which is sent to the Forensic & Analytical Science Service (FASS) for confirmatory analysis, and it is based on that confirmatory test that a driver is charged with an offence.

Comparison between countries and the legality of driving after consumption of cannabis medicines is difficult due to the different regulatory systems in use and the different status of cannabis products used for medical purposes.

In several countries, it is prohibited to drive with THC in blood or serum at certain levels, regardless of impairment or whether the medicine is used under medical supervision or not. There are also laws against driving impaired. Generally, however, there is no differentiation between THC levels permitted for products prescribed or recommended by a doctor and those used for other purposes.

Concerns have been expressed that persons who have taken prescribed cannabis medicines may commit an offence in NSW by driving, even when not impaired, because of the potential for THC to be detected in roadside saliva tests. This is unique to THC, due to its widespread recreational use and because currently no other prescribed medicines are detected or unlawful to drive *unless* there is impairment in NSW.

A number of approaches are in place overseas:

### 1. **Impairment**

In many jurisdictions it is unlawful to drive when impaired due to use of pharmaceuticals. This includes New Zealand, where it is unlawful to drive when impaired due to any drug or circumstance.<sup>2</sup> This is also true in Australia. Impairment is usually determined by police and based on a sobriety assessment and blood/urine samples (not collected at the roadside).

### 2. **Permitted levels**

In some overseas jurisdictions it is unlawful to drive with certain blood or serum levels of several prescription medicines, whether or not the person is considered impaired. The same levels apply to cannabis medicines and recreational cannabis. This is the case, for example, in [Canada](#), the [Netherlands](#) and [Germany](#) for the 'medicinal use' of THC, although in Canada the police must have reasonable suspicion the person may have consumed drugs. These laws are in effect in several states of the USA for one or more drugs and are referred to as 'per-se' laws.

Threshold THC levels vary from jurisdiction to jurisdiction and typically require blood samples to be collected by an authorised sample taker, which is comparatively resource intensive and invasive. Roadside oral fluid testing, in contrast, can be delivered quickly and efficiently at the roadside. This type of testing provides a reliable indicator of recent use, with presence of THC above a threshold level confirmed through laboratory analysis of the oral fluid.

Use for medicinal purposes is not a defence in some jurisdictions where permitted levels are in operation. There is no way to verify from blood levels if some or all the THC present is due to medicinal cannabis use alone or use of illicit cannabis. When toxicology results are interpreted, consideration of the entire case scenario may be required, especially when an interaction may be occurring between prescribed and non-prescribed substances and alcohol.<sup>3</sup> Unlike alcohol, a direct relationship between blood levels of THC and levels of driving impairment has not yet been established.<sup>4</sup>

### 3. **Medical defence**

In some jurisdictions where the cannabis product is taken as prescribed, and no impairment is obvious, an exemption exists. In the [UK](#) and [NZ](#) there is a medical defence where a prescribed medication is detected, and the medication is being taken as prescribed and the driver is unimpaired. Typically, drivers would be required in court to prove they were compliant with their prescription and were not impaired. This is typically demonstrated through blood test results and police sobriety assessments.

### 4. **Prohibition of the combination of THC (whether medicinal or recreational) and other drugs, particularly alcohol**

In the Netherlands [any level of THC when combined with other drugs \(including alcohol\) at any level is prohibited](#). In Germany cannabis users are prohibited from [driving with any alcohol](#). This approach reflects the documented experience worldwide of the frequency of detection of levels of drugs in combination in crashes, and the interplay of drugs and alcohol which significantly increases the risk of a crash.<sup>5</sup> Again, there is no differentiation between the reasons why a person may have THC in their bloodstream (prescribed or use of cannabis products for therapeutic or recreational reasons).

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## References

- <sup>1</sup> Lintzeris N, Mills L, Abelev SV, Suraev A, Arnold JC, McGregor IS. Medical cannabis use in Australia: consumer experiences from the online cannabis as medicine survey 2020 (CAMS-20). *Harm Reduct J.* 2022 Jul 30;19(1):88. doi: 10.1186/s12954-022-00666-w. PMID: 35907959; PMCID: PMC9338505.
- <sup>2</sup> NZ Transport Agency Medication
- <sup>3</sup> Jones AW, Mørland JG, Liu RH. Driving under the influence of psychoactive substances - A historical review. *Forensic Science Review.* 2019 Jul;31(2):103-140. PMID: 31270058.
- <sup>4</sup> NSW Health 2022 Prescribed cannabis medicines and fitness to drive
- <sup>5</sup> Li G, Brady JE, Chen Q. Drug use and fatal motor vehicle crashes: a case-control study. *Accid Anal Prev.* 2013 Nov;60:205-10. doi: 10.1016/j.aap.2013.09.001. Epub 2013 Sep 8. PMID: 24076302.