



## POLICY

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### Medicinal Cannabis

#### Position

The Pharmacy Guild of Australia (the Guild) supports the amended regulation that will ensure supply and patient's use of medicinal cannabis involves therapeutic input from a trained health professional such as a pharmacist.

The Guild supports ongoing training and development of the health workforce, particularly the professional education and training in relation to therapeutic use of medicinal cannabis preparations that has been made available to support pharmacists and improve outcomes for their patients.

The Guild supports pharmacists who have demonstrated the competency to undertake extemporaneous compounding of medicinal cannabis products to continue this practice.

The Guild considers a patient's regular community pharmacy the most appropriate location for supply of medicinal cannabis products and opposes the sale and supply of medicinal cannabis products via non-health care settings, such as health food stores, supermarkets, or non-pharmaceutical dispensaries, where the patient cannot readily access the advice of a health care professional.

The Guild would support mandatory recording for the Schedule 3 supply of medicinal cannabis products, including in the pharmacy's dispensing software and in real time prescription monitoring (RTPM) systems in use across Australia.

The Guild supports evidence-based use of medicines and ongoing high-quality clinical trials into the efficacy and safety of medicinal cannabis.

The Guild remains opposed to illicit and unregulated manufacture, supply and use of all naturally-occurring and synthetic cannabis preparations and derivatives.

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## Background

### Medicinal Cannabis

The cannabis sativa plant contains at least 60 active chemicals known as cannabinoids, several of which are biologically active, with delta-9-tetrahydrocannabinol (THC) responsible for most of the psychoactive effects of cannabis<sup>1</sup>. Most medicinal cannabis products contain the cannabinoids THC and cannabidiol (CBD), with the scheduling of these poisons reflecting the requirement for more restrictive regulatory controls for THC. In addition to preparations containing plant derived cannabinoids, preparations containing laboratory produced synthetic cannabinoids are also available.

### Scheduling

Proponents of medicinal cannabis use in Australia argued that CBD in concentrations of 98% or more, with a limit of the psychoactive THC component to 2% should not be regulated as a Schedule 4 substance, but as a listed, assessed-listed or a registered medicine (depending on the level of therapeutic claim) in the Australian Register of Therapeutic Goods (ARTG). This is consistent with recommendations by the World Health Organisation (WHO)<sup>2</sup>, and as such, the TGA has amended the Poisons Standard to enable pharmacists to supply certain cannabidiol preparations comprising at least 98% CBD as Schedule 3 or Pharmacist Only medicines from 1 February 2021. This Schedule change improves patient access to cannabidiol (CBD) preparations while still maintaining input and oversight from a health professional and balancing public safety.

The Schedule 3 entry applies to CBD in oral, oromucosal and sublingual preparations where CBD comprises 98% or more of the total cannabinoid content and THC comprises no more than 1% of the total cannabinoid content. CBD in these preparations can be either plant derived or, when synthetic, contain only the (-) CBD enantiomer. The maximum recommended daily dose of CBD is 150mg or less, in packs containing no more than 30 days' supply and packed in blister packaging or in a container fitted with a child-resistant closure.<sup>3</sup> Patients supplied CBD products as a Schedule 3 medicine must be aged 18 years and over.

Medicinal cannabis products where CBD comprises 98% or more of the total cannabinoid content and where any other cannabinoid, including THC, comprise 2% or less of the total cannabinoid content continue to be classified as Schedule 4 medicines. Any medicinal cannabis products that do not meet the requirements of the Schedule 4 entry remain Schedule 8 Controlled Drugs.

### Compounded medicinal cannabis

The Guild believes it to be important for both approved and unapproved medicinal cannabis products supplied in Australia to be as high quality and safe as possible. Regarding the compounding of medicinal cannabis, the Guild supports pharmacies adhering to the Pharmacy Board of Australia's *Guidelines on compounding of medicines* as a standard for compounding all medicines in Australia.

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<sup>1</sup> National Cannabis Prevention and Information Centre (NCPIC) 'What is Cannabis' factsheet (2011)

<sup>2</sup> [https://www.who.int/medicines/access/controlled-substances/UNSG\\_letter\\_ECDD41\\_recommendations\\_cannabis\\_24Jan19.pdf?ua=1](https://www.who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf?ua=1)

<sup>3</sup> Therapeutic Goods Administration 2020, Notice of final decisions to amend (or not amend) the current Poisons Standard – cannabidiol, 15 December 2020, *Commonwealth Department of Health*. <https://www.tga.gov.au/scheduling-decision-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-cannabidiol> Last accessed 15 February 2021

The *Guidelines on compounding of medicines* states:

A compounded medicine should be prepared only in circumstances where:

- an appropriate commercial product is unavailable
- a commercial product is unsuitable (e.g., if a patient experiences an allergy to an excipient in the commercial product), or
- when undertaking research sanctioned by a recognised human research ethics committee.<sup>4</sup>

In these guidelines, 'commercial product' and 'commercially available' refer to medicines that are listed on the ARTG that are able to be accessed by pharmacists via a wholesaler or directly from the manufacturer.<sup>5</sup>

## **Medicinal use**

### ***Patient access***

Patient access to medicinal cannabis in Australia has gained more prominence in public debate in recent years. The Guild considers the patient's regular community pharmacy to be the most appropriate location for the supply of medicinal cannabis products along with the supply of the patient's other therapeutic products and services. Pharmacists should ensure that they provide counselling and advice to support patients in choosing safe and effective medicinal cannabis products.

Until recently, the majority of medicinal cannabis products accessible to patients in Australia were unapproved products, and as such these products could only be accessed through special pathways available for unapproved medicines. Unapproved products are those that have not been assessed by the Therapeutic Goods Administration (TGA) for safety, quality and efficacy and are therefore not eligible to be included in the ARTG. For this reason, it is important that patients access medicinal cannabis products through reputable channels, such as their regular community pharmacy, to reduce the risk of potential harm from products purchased from unknown sources.<sup>6</sup>

### ***Evidence-based medicine***

Although medicinal cannabis has been used for a long time and there is a large amount of purported evidence of efficacy, the Guild believes that medicinal cannabis products should be held to the same standard of quality, safety and efficacy as other therapeutic substances, in line with the Quality Use of Medicines and the National Medicines Policy.

While medicinal cannabis has been reported to be effective in the treatment of many conditions including anxiety, depression, epilepsy, chronic pain and insomnia, there remains a significant scientific evidence gap relating to the safety, effectiveness, routes of administration and formulation of medicinal cannabis products<sup>7</sup>. There is a lot of anecdotal evidence from people who have used medicinal cannabis-containing products but not any high-quality level trials data that supports its effectiveness in the treatment of any of these indications. It is also unclear what the therapeutic dose or the concentration of CBD and other components such as THC, was in these consumed products. Hence, it is difficult to draw conclusions about the efficacy or the dose response curve of medicinal cannabis for any of the suggested conditions.

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<sup>4</sup> Pharmacy Board of Australia (March 2015). Guidelines on compounding of medicines. <https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx>

<sup>5</sup> Pharmacy Board of Australia, Frequently asked questions for pharmacists on the compounding of medicines. [https://www.google.com/search?q=pharmacy+board+compounding+guidelines&rlz=1C1GCEB\\_enAU927AU928&og=pharmacy+board+compounding+guideline&aqs=chrome.0.0i457j69i57j0i22i30.4910j0j7&sourceid=chrome&ie=UTF-8](https://www.google.com/search?q=pharmacy+board+compounding+guidelines&rlz=1C1GCEB_enAU927AU928&og=pharmacy+board+compounding+guideline&aqs=chrome.0.0i457j69i57j0i22i30.4910j0j7&sourceid=chrome&ie=UTF-8)

<sup>6</sup> <https://www.tga.gov.au/behind-news/tga-warns-consumers-about-potential-harm-unlawfully-supplied-medicinal-cannabis>

<sup>7</sup> Victoria State Government, Australian Medicinal Cannabis Study <https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicinal-cannabis/medicinal-cannabis-study> last accessed 15 February 2021

The TGA's recent review<sup>8</sup> of the safety of CBD containing products indicates that CBD appears to be relatively safe when used as prescribed, in low doses, but it does not address the question of efficacy. Given the lack of evidence for the purported clinical indications, the Guild would be supportive of ongoing high-quality clinical trials to build the body of evidence for the effectiveness and therapeutic use of CBD.

Additionally, evaluations of adverse effects associated with medicinal cannabis use have primarily focused on short-term use for the treatment of nausea and vomiting, and appetite, pain and spasticity in multiple sclerosis. There is limited information on the adverse effects associated with long-term use of medicinal cannabis. The Guild supports pharmacovigilance activities and high-quality clinical trials focusing on the adverse effects associated with long-term use of medicinal cannabis to assess the long-term safety of patient use.

The Guild welcomes any progress in new treatments that have the potential to improve the quality of life of people who are chronically or terminally ill and who are not adequately responding to existing therapies. We support ongoing research to establish the evidence for therapeutic effectiveness of medicinal cannabis in the treatment of debilitating symptoms of conditions such as multiple sclerosis, epilepsy, cancer and cancer treatment, HIV/AIDS, and severe neuropathic or arthritic pain.

#### ***Drug interactions and safety concerns***

There are reports of significant drug interactions of medicinal cannabis and its derivatives through the cytochrome P450 (CYP450) metabolism pathways, which are also the metabolism pathways for many prescription medicines often used to treat or manage the same conditions as those of medicinal cannabis. This poses a significant risk of drug interactions and adverse events if medicinal cannabis is used concurrently with these medicines.

Self-selection of medicinal cannabis containing substances could lead to harm in patients who may be taking prescribed medicines for the treatment or management of these same conditions, which would be more common than exceptional, as many of these conditions are chronic and incurable. Hence, self-selection without the input of a health professional could lead to unintentional harm, despite written warning labels, and is opposed by the Guild.

#### ***Recording Supply***

In addition to medicinal cannabis being supplied as a Schedule 8 or Schedule 4 medicine, the Guild would welcome mandatory recording for the Schedule 3 supply of medicinal cannabis products, including in the pharmacy's dispensing software and real time prescription monitoring (RTPM) systems in use across Australia. Recording of Schedule 3 supplies in RTPM systems will enable monitoring of compliance with the maximum recommended daily dosing of 150mg or less, as set out in the Poisons Standard. RTPM systems are currently used to monitor supplies of certain medicines and include SafeScript in Victoria, ScriptCheck in South Australia, DORA in Tasmania and Canberra Script in the ACT. QScript and NTScript are currently in development for use in Queensland and the Northern Territory, respectively. Western Australian state health regulators have also committed to undertaking development of RTPM technologies.

#### ***Education and Training for Pharmacists***

As with any new class of medicine, professional training and development is essential to enable pharmacists to support patients in the quality use of medicinal cannabis products. Guild Learning and Development has developed a CPD-accredited module for pharmacists, which provides an introduction to medicinal cannabis.

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<sup>8</sup> Therapeutic Goods Administration 2020, Safety of low dose cannabidiol, *Commonwealth Department of Health*. <https://www.tga.gov.au/alert/review-safety-low-dose-cannabidiol>. Last accessed 28 April 2020.

The Guild is supportive of opportunities for inter-professional education for doctors, pharmacists and other health care professionals so that everyone is aware of each other's role in supporting patients to use medicinal cannabis products safely and effectively. Furthermore, State/Territory and Commonwealth governments should provide financial support for the training and education of pharmacists and other health professionals, to help meet regulatory requirements.

### **Cannabis use and mental health disorders**

The potential harms associated with cannabis use are dependent on two main factors above all others; the age at which cannabis use first began and the pattern of use, including frequency, dose and duration or use. It is well documented that cannabis use under the age of 18 can have potential negative impacts on key stages of brain development; it can also impact on emotional experiences at all ages. People using cannabis at least weekly are at greater risk of potential harm, as are those using a bigger or more potent dose. This increased risk of potential harm is due to the likelihood that individuals using cannabis more frequently or at more potent doses are likely to be ingesting more THC, which exerts the psychoactive effects of cannabis and can affect the areas of the brain responsible for the regulation of emotional experiences.<sup>9</sup>

Research into the effects of cannabis use to treat symptoms of mental health disorders such as anxiety, depression, attention deficit hyperactivity disorder, schizophrenia and bipolar disorder is increasing, however there is still a lack of high-quality clinical research that supports the use of cannabis as a treatment for these disorders.<sup>10</sup> Available research indicates that cannabis use may worsen the course of bipolar disorder, and those who are predisposed to experiencing psychosis (a common symptom of schizophrenia) may be at an increased risk of cannabis-induced psychosis.<sup>11</sup> Evidence suggests that cannabis use will bring forward diagnosis of psychosis by an average of 2.7 years.

A 2014 meta-analysis determined that using cannabis placed an individual at moderate risk of developing depression, although it could not clearly state whether cannabis use was causing depression or an associated factor of social problems that increased risk of depression.<sup>12</sup>

### **Non-medicinal and illicit cannabis use in Australia**

The AIHW 2019 National Drug Strategy Household Survey found that cannabis was the most commonly used illicit drug in Australia, with 11.6% of Australians having used cannabis in the last 12 months. Cannabis was also the most frequently used illicit drug, with 37% using it weekly or more often.<sup>13</sup>

#### ***Treatment to reduce the non-medicinal and illicit use of cannabis***

The Guild believes that there is a need for a range of evidence-based treatments for reducing harmful patterns of cannabis use. The Guild also believes that there is a need to improve the knowledge and skills of health professionals, including pharmacists, relating to harms associated with cannabis use, the management of cannabis dependence and the treatment options available. The Guild also supports programs that recognise community pharmacists as being part of the primary health care team, in particular programs that involve community pharmacists in any coordinated care planning for patients to address their substance misuse.

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<sup>9</sup> <https://ndarc.med.unsw.edu.au/blog/does-Cannabis-cause-mental-illness>

<sup>10</sup> <https://bmcp psychiatry.biomedcentral.com/articles/10.1186/s12888-019-2409-8>

<sup>11</sup> National Academies of Sciences, Engineering and Medicine. (2017) The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.

<sup>12</sup> S Lev-Ran et al. (2014) The association between cannabis use and depression: a systematic review and meta-analysis of longitudinal studies.

<sup>13</sup> Australian Institute of Health and Welfare 2019 National Drug Strategy Household Survey report

The Cannabis Information & Support Centre (previously National Cannabis Prevention and Information Centre (NCPIC)), in conjunction with the NSW Branch of the Guild, developed pharmacy-based interventions for cannabis use-related difficulties. This resource is available for pharmacists to access to support patients and family seeking information via the Centre's website [Pharmacy-based interventions for cannabis use-related difficulties](#).<sup>14</sup>

### **National Drug Strategy 2017-2026**

Under the current National Drug Strategy 2017-2026<sup>15</sup> cannabis is included among the priority drug types associated with the most harm in Australia. Medicinal use of cannabis has not been explored within the Australian legislative context as part of the Strategy.

The Strategy provides a national framework which:

- identifies national priorities relating to alcohol, tobacco and other drugs,
- guides action by governments in partnership with service providers and the community, and
- outlines a national commitment to harm minimisation through balanced adoption of effective demand, supply and harm reduction strategies.

## **Related Policies**

Nil

## **Authority**

### **Endorsed**

National Council – September 2021

National Council – June 2015

National Council – November 2014

National Council – November 2012

National Council – June 2007

National Council – November 2003

### **Reviewed**

June 2021 – Policy and Regulation Sub-Committee

April 2015 – Policy and Regulation Sub-Committee

October 2014 – Policy and Regulation Sub-Committee

October 2012 – Policy and Regulatory Affairs Committee

May 2007 – Policy/Government/Communications Committee

May 2007 – Addiction Care Committee

November 2003 – Strategic Policy/Rural and Professional Services Committee

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<sup>14</sup> [Pharmacy-based interventions for cannabis use-related difficulties, https://cannabissupport.com.au/pharmacy-based-interventions-for-cannabis-use-related-difficulties/](https://cannabissupport.com.au/pharmacy-based-interventions-for-cannabis-use-related-difficulties/)

<sup>15</sup> National Drug Strategy 2017-2026 <http://www.health.gov.au/internet/main/publishing.nsf/Content/ministerial-drug-alcohol-forum>