



Inquiry into Cannabis and Hemp

Alcohol and Drug
Foundation

Submission

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ABOUT THE ALCOHOL AND DRUG FOUNDATION

The Alcohol and Drug Foundation (ADF) delivers evidence-based approaches to minimise alcohol and other drug harm. We recognise the power of strong communities and the important role they play in preventing problems occurring in the first place. A community-centric approach is at the heart of everything we do.

The ADF thanks the Committee for the opportunity to contribute to this Inquiry.

CLARIFICATION OF TERMS: HEMP, CANNABIS, AND MEDICINAL CANNABIS PRODUCTS

The *Cannabis sativa* plant has been altered by human selection over the thousands of years it has been variously used as a food, fibre, intoxicant, and medicine, resulting in both non-narcotic and narcotic varieties of the plant.¹ For clarity, the ADF defines the terms used in this submission as follows.

Hemp: non-narcotic plant grown to make a variety of products including but not limited to hemp fibre, hemp food products such as hemp oil and hemp seeds, and animal feed. Hemp is currently grown as an industrial crop in Australia, including Western Australia, under licence from the relevant state government.² Under the *Industrial Hemp Act 2004*, industrial hemp is defined as containing no more than 1% tetrahydrocannabinol (THC) in the leaves and flowers of the plant.³

Cannabis: narcotic plant grown primarily for use as an intoxicant with high THC content. Levels of other cannabinoids, such as cannabidiol (CBD), will depend on the variety of the plant being grown. Illegal to grow, sell, and possess in Western Australia. Commonly called marijuana.

Medicinal cannabis products: products made of, derived from, or synthesised from the cannabis plant to treat a range of health conditions under medical supervision. Medicinal cannabis products are produced to strict quality standards, contain known ratios of cannabinoids (the active chemicals), and are taken under the supervision of a medical practitioner. Products vary in their composition and may contain CBD-only (non-intoxicating) or varying ratios of CBD and THC.

2.A THE CURRENT BARRIERS TO PHARMACEUTICAL AND NUTRACEUTICAL USE OF CANNABINOID PRODUCTS

Access to medicinal cannabis products

Medicinal cannabis products are currently available in Australia through the TGA's Special Access Schemes (SAS) and the TGA's Authorised Prescriber Scheme.

Most prescriptions are made through SAS,⁴ which facilitates prescribing through either:

- Category A: for medical practitioners on behalf of seriously ill patients
- Category B: for medical practitioners if patients do not fit SAS-A definitions. The application must include a patient diagnosis, a clinical justification for the proposed use, and safety and efficacy data. SAS-B is the most common path for prescribing medicinal cannabis.

(Note: under the 'Special Access Scheme' for unapproved medicines, the TGA does not endorse the use of, or accept responsibility for, any adverse consequences of treatment.)

The prescriber must specify what clinical indication or condition they are prescribing the product for and applications are then assessed on this clinical information.

The Authorised Prescriber Scheme (APS) facilitates prescribing to a predetermined class of appropriate patients with approved treatment condition, such as paediatric epilepsy, multiple sclerosis and palliative care.

Some patients may also be able to access medicinal cannabis through a clinical trial if their clinical condition is currently being studied and they meet the study inclusion criteria.

In Australia, clinical trials are underway for a variety of diagnoses.

In 2019, the Australian Government announced \$3 million to examine the benefits of medicinal cannabis in managing pain and reducing symptoms and side effects of cancer patients.⁵ There are also a range of trials investigating treatment of insomnia, anxiety, methamphetamine dependence, post-traumatic stress disorder, and Tourette's syndrome.⁶

These trials are essential for building the evidence base relating to the appropriate and safe clinical use of medicinal cannabis, its efficacy, and side effect monitoring.

Available medicinal cannabis products

More than 100 different medicinal cannabis products have been accessed in Australia, including dried cannabis flower, oils, and pharmaceutical preparations.⁷

Currently, there are two cannabis products listed on the Australian Register of Therapeutic Goods (ARTG):

- nabiximols (brand name: Sativex) which contains THC and CBD
- cannabidiol (brand name: Epidyolex) which is a CBD-only oil preparation.

Other products are considered unregistered and may contain either, or both, THC and CBD in various ratios. These products may still be accessed in Australia through SAS and APS, if approved. The addition of cannabis products to the ARTG was raised in a Senate Inquiry, with one submission noting that:

"The investment into preparing such a dossier is prohibitive, running into tens of millions of dollars, and not commercially viable when it is weighed against the inability to obtain [intellectual property] protection and the difficulties in obtaining PBS listing."⁸

However, the requirement for listing on the ARTG is not unattainable as there are two cannabis products now listed.

Cost as a complex barrier

Currently no medicinal cannabis products are listed on the Pharmaceutical Benefits Scheme (PBS), which means they cannot be accessed at a Government-subsidised price, making some medicines prohibitively expensive.

For a medicine to receive PBS listing, it must receive:

- 1) TGA approval after determining the medicine is effective and safe
- 2) Pharmaceutical Benefits Advisory Committee (PBAC) approval after considering effectiveness, safety and cost, including in comparison with other treatments

3) the Minister for Health's approval.

Maintaining the integrity of this system is important to ensure that all medications approved by the TGA have a robust safety profile.

Following the registration of Epidyolex (cannabidiol) on the ARTG, the manufacturer GW Pharmaceuticals and its partner, Chiesi Australia, announced that they will work with Australia's Pharmaceutical Benefits Advisory Committee (PBAC) to see Epidyolex listed on the PBS.⁹

This is important on compassionate grounds, the current cost of medicinal cannabis can be a significant barrier, particularly for those who need high-dose CBD medicines (such as Epidyolex) to treat some paediatric epilepsies.⁸

The prohibitive cost is an issue for many patients who instead source herbal cannabis from a non-prescribed supply.⁷ This means that they will not receive a medical-grade product with known ratios of cannabinoids and will not receive it under medical supervision.⁷ Apart from residents of the ACT, it also puts a person at risk of being criminalised for possessing illegal cannabis.

The cost of medicinal cannabis products is a challenging topic that requires consideration of both the human right to access healthcare unlimited by socioeconomic status while protecting the integrity of Australia's pharmaceutical regulatory system and the PBS.

Other barriers to accessing medicinal cannabis products

Stigma and prescribing barriers

Cannabis has had a long and colourful global history, and perceptions of its medicinal applications have changed over time. In Australia, there is a high level of support for medicinal cannabis. However entrenched stigma about cannabis, and medicinal cannabis' association with illicit drug use, may deter people from seeking a prescription or disclosing that they have a legitimate prescription for cannabis.

The Senate Community Affairs References Committee Inquiry into 'Current barriers to patient access to medicinal cannabis in Australia'⁸ report suggests that stigma could be an issue when patients raised the possibility of using medicinal cannabis with their GP or specialist. The report notes that "at worst, the committee was told that patients were simply rebuffed and felt ostracised by the negative or dismissive attitude of the clinician they consulted."⁸ The report states that stigma in the health profession towards medicinal cannabis products needs to change because it can undermine trust with patients. No one should feel stigmatised for considering potential medical treatment with cannabis products.⁸

To address the stigma around medicinal cannabis products and increase knowledge of how it can be accessed, the Senate Community Affairs References Committee recommended:⁸

- developing targeted education and public awareness campaigns
- providing both online and in-person training options around medicinal cannabis for medical practitioners
- mandatory inclusion of education on medicinal cannabis and the endocannabinoid system in medical schools' curriculum
- developing patient-focused resources that explain how to access medicinal cannabis.

The negative impact of stigma and discrimination cannot be understated.

While it is illegal to promote the use of any Schedule 4 or 8 medication, appropriate information given to patients to share with others may help reduce stigma. Educating the public that medicinal

cannabis products are distinct from illicit cannabis may also help to address inaccurate perceptions.

The Senate Community Affairs References Committee report also states that without resources to support patients and prescribers in accessing medicinal cannabis products, “patients will continue to miss out on potentially beneficial treatment options, and, worryingly, may continue to turn to the black market in a bid to access medicinal cannabis products.”⁸

An online survey conducted by the Lambert Initiative^a two years after the legalisation of medicinal cannabis found that 47.8% of respondents acquired cannabis for medicinal purposes from a non-prescribed source because they did not know a medical practitioner who was willing to prescribe.

Another 18.4% reported that their practitioner was not interested or unwilling to prescribe it, and 12.7% preferred to keep their use of cannabis confidential from their practitioner.⁷ Other reasons included not knowing cannabis could be legally prescribed (32%), its prohibitive cost (21.2%) and having a preference for illicit cannabis (9.5%).⁷

Roadside drug testing

The current roadside drug testing regime may also be a barrier to the uptake of medicinal cannabis products by some patients. Currently, a prescription for a medicinal cannabis product does not exempt drivers who test positive for THC even if they did not appear to be impaired at the time of testing.

The ADF recognises the critical role that the police play in road safety and that drug driving poses serious risks. THC intoxication is known to decrease a person’s ability to drive. However, roadside drug tests only detect the presence of a limited number of drugs in a person’s system (including THC) but do not establish impairment. This can mean that a person taking their medicinal cannabis product as prescribed may not be impaired at the time of driving but could potentially test positive for THC.

Advocacy on this issue is ongoing, such as the Drive Change initiative,^b but the roadside drug testing regime as it stands may be a barrier to potential medicinal cannabis product patients who drive and are concerned that a prescription does not offer them a defence for testing positive for THC.

Access to low THC hemp seed foods

In 2017, the Food Standards Code was amended by Food Standards Australia New Zealand (FSANZ) to allow for the sale of low THC hemp seed foods.¹⁰

To the ADF’s knowledge, low THC hemp seed products including hulled hemp seeds, hemp seed oil, hemp oil capsules, and hemp as an addition to flax meals, granola, and pasta are available at major supermarket chains. We are not aware of any adverse events that have occurred as a result of the availability of low THC hemp seed products.

^a Limitations of the survey design (online, convenience sampling, recruiting from online medicinal cannabis forums) might have resulted in over-estimates.

^b <https://www.drivechangemc.org.au/>

Access to cannabidiol (CBD) products in pharmacies

In 2020, the TGA down-scheduled some low-dose CBD preparations to Pharmacist Only Medicines (schedule 3) to allow for up to 150mg per person per day to be sold via pharmacists.¹¹ CBD is not psychoactive, and historically has not been prohibited in some other countries, such as the UK, due to its low potential for harm.¹²

Consumers should be aware that medicinal CBD products used in treating conditions such as epilepsy are typically prescribed in much higher doses than will be available from pharmacists and these products are not a replacement for a prescribed medicinal cannabis product.

2.B MEDICINAL CANNABIS, ITS PRESCRIPTION, AVAILABILITY, AND AFFORDABILITY

While medicinal cannabis products were discussed under the previous term of reference the ADF wishes to be clear that non-prescribed cannabis being used for perceived medicinal purposes is not the same as the use of a prescribed medicinal cannabis product. The ADF does not encourage people to self-diagnose or to self-mediate with cannabis purchased from the illegal market.

There is no replacement for the expertise, guidance, and ongoing support offered by a medical practitioner or the strict quality standards that medicinal cannabis products are produced to.

We have concerns over the quality of the products sold on the illegal market and if those products in fact contain the levels and ratios of cannabinoids that may be claimed. We are also concerned about patients using illegal cannabis without the support and monitoring of a medical practitioner, who would otherwise be able to assist with dosing, managing negative side effects, and an understanding of how the use of cannabis may affect any conditions the patient may have, or affect any other medications they may be taking.

Physicians are best placed to determine the appropriateness of medicinal cannabis treatments based on their patient's current needs and medical history.

The ADF recognises that cost is currently a significant barrier for many potential patients, and we hope to see this resolved in time as medicinal cannabis products continue to go through the appropriate levels of research and approvals that are required of other medicines seeking PBS listing.

We also note a positive increase in the variety of resources to support patients and prescribers around medicinal cannabis products, including guidance documents produced for the TGA, information published by Australian Prescriber including a podcast,^c RACGP webinars,^d the NSW Cannabis Medicines Prescribing Guide,^e and resources from NPS Medicinewise.^f Additionally, as of February 2021, Health Cert Education is also offering an online Professional Diploma Program in Medicinal Cannabis, which has been reviewed by Griffin University and endorsed by the RACGP.¹³

^c <https://www.nps.org.au/australian-prescriber/articles/prescribing-medicinal-cannabis>

^d <https://www.racgp.org.au/education/professional-development/online-learning/webinars/medicinal-cannabis>

^e <https://www.australiancannabinoidresearch.com.au/resources>

^f <https://www.nps.org.au/professionals/medicinal-cannabis-what-you-need-to-know>

2.C THE POTENTIAL BENEFITS AND RISKS OF PERMITTING INDUSTRIAL HEMP FOR HUMAN CONSUMPTION

In 2017, the Food Standards Code was amended by Food Standards Australia New Zealand (FSANZ) to allow for the sale of low THC hemp seed foods.¹⁰

To the best of the knowledge of the ADF, there are no risks associated with permitting low THC hemp seed foods for human consumption in accordance with the Food Standards Code. Due to the negligible amount of THC permitted in industrial hemp, low THC hemp seed foods pose no risk for producing intoxicating effects. There appear to be a number of nutritional benefits from the consumption of low THC hemp foods, including a high protein content as well as omega-6 and omega-3 fatty acids.

Although outside the scope of this Inquiry, hemp appears to have suffered as a product due to an association with narcotic cannabis. We reiterate that the two plants vary greatly in terms of the amount of THC present, with industrial hemp posing no risk as an intoxicant. Industrial hemp appears to be a versatile, environmentally friendly crop that should be understood as distinct from narcotic cannabis.

INQUIRY INTO THE USE OF CANNABIS IN VICTORIA

In August 2021, the Legislative Council Legal and Social Issues Committee tabled their final report and recommendations following the Inquiry into the use of cannabis in Victoria.

Much of the evidence considered in that report, as well as the recommendations, will also be relevant to discussions about cannabis in Western Australia and so the report is likely to be of interest to this Committee:

https://www.parliament.vic.gov.au/images/stories/committees/SCLSI/Inquiry_into_the_use_of_Cannabis_in_Victoria/Report/LCLSIC_59-07_Use_of_cannabis_in_Vic.pdf

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