Clinical Memorandum

Therapeutic use of medicinal cannabis products

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The Royal Australian & New Zealand College of Psychiatrists

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Purpose

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) has developed this memorandum to provide information for psychiatrists about the medicinal use of cannabis products.

Key messages

- Although there is increasing public and medical interest in medicinal cannabis, the evidence upon which to base an assessment of the efficacy, effectiveness and safety of medicinal cannabis products is limited.
- There is insufficient evidence to support medicinal cannabis as a treatment for anxiety and other mental disorders, and there is no substantial evidence to support its use outside of properly approved research trials for these disorders.
- Further high-quality research regarding the use of medicinal cannabis for the treatment of mental disorders conducted under standard research trial conditions is needed.
- Medicinal cannabis used outside of formal research trials requires careful evaluation of use, prescribed only in rare circumstances, after other treatments have been tried without benefit, and with outcomes recorded.
- The prescription of medicinal cannabis for any condition should take into consideration the risks of use in including potential for misuse, dependence, side effects, and polypharmacy.
- The use of prescribed high potency delta-9 tetrahydrocannabinol (THC) containing medicinal cannabis products may cause high risks for people with psychotic predisposition, requiring careful patient selection.
- The RANZCP is concerned by the widespread smoking of prescribed medical cannabis products, with the inherent health risks to lung and general health from smoking.
- Regulatory changes to improve access to medicinal cannabis products in Australia and New Zealand have been based on a perception of low risk or harm rather than evidence of effectiveness. RANZCP is concerned that potential harms, particularly high potency THC containing medicinal cannabis products, have been overlooked.
- Refinements to legislation for accessing medicinal cannabis products should be considered in line with available evidence and harm minimisation strategies.

Definitions and scope

Cannabis is the term given to products derived from elements of the cannabis plant used for medical or recreational purpose. Cannabis is known by a range of alternative terms (e.g. marijuana) but most medical producers and legislation use ‘cannabis’ as the preferred term.

Medical cannabinoids include a variety of chemical compounds, some synthetic and some extracted from the cannabis plant, which have been developed for medical use.

The cannabis plant contains many cannabinoids; the best known of which are delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD). [1] THC is the psychoactive part of cannabis that produces a 'high'. CBD has no psychoactive properties.

The terms medicinal cannabis and cannabinoids are used interchangeably when referring to the products derived from the cannabis plant for a medical purpose. This document predominantly uses the term medicinal cannabis, as that is the term used by both the Therapeutic Goods Administration (TGA) in Australia and the Ministry of Health in New Zealand.

This memorandum does not relate to the decriminalisation of cannabis for general cultivation or recreational use.

Background

There is a global trend towards increasing use of cannabis-based products for therapeutic or medical reasons. [2] Governments at both Commonwealth and state and territory levels in Australia, and in New Zealand, have implemented legislative and policy change to allow the cultivation, manufacture, prescribing and dispensing of medicinal cannabis products in Australia [1] and New Zealand [3] for the management of medical conditions.

Given the public interest in medicinal cannabis, psychiatrists and other medical doctors are increasingly being asked to prescribe these products. Prescribing and use of medicinal cannabis requires careful consideration of relevant issues.

Evidence

- Recent reviews and analyses indicate there may be some therapeutic benefits of medicinal cannabis products in certain conditions although further research on their treatment efficacy and longer-term side effects are warranted.[4, 5]

- There is currently good evidence for use of medicinal cannabis only in certain forms of childhood epilepsy.[6]

- A systemic review and meta-analysis into medical cannabis for the treatment of mental disorders and symptoms of mental disorders reported that there is very little evidence to suggest that cannabinoids improve depressive disorders and symptoms, anxiety disorders, attention-deficit hyperactivity disorder, Tourette syndrome, post-traumatic stress disorder, or psychosis.[7] This study further found there to be very low quality evidence that pharmaceutical THC (with or without CBD) leads to a small improvement in symptoms of anxiety among individuals with other medical conditions. Further reviews in the field of medicinal cannabis highlight that evidence is nascent and unconvincing and recommend that further high-quality studies directly examining the effect of cannabinoids on treating mental disorders are needed. [8, 9]

- Despite growing community and scientific interest, a recent systematic review identified limited and generally poor-quality evidence for the efficacy of cannabinoid-based products (medicinal cannabis) in neuropsychiatric and neurodevelopmental disorders in children and adolescents including anxiety disorders, autism spectrum disorder, foetal alcohol spectrum disorder, intellectual disability, mood disorders, post-traumatic stress disorder, and Tourette syndrome.[10] A systematic review looking at cannabis use in autism spectrum disorder highlighted potential promising effects but identified the need for RCTs to clarify findings.[11] Large rigorous RCTs are required to inform clinical care.[10]

- Research is ongoing into the potential utility of cannabidiol (CBD) in the treatment of mental illness and as a potential harm reduction strategy for people with problematic substance use.[12, 13] Research into the anxiolytic and somnolent properties of medical cannabis that

may have some medical use and potentially spare use of benzodiazepines and z-drugs would benefit from further exploration.[14]

- Further research in the form of high-quality RCTs are required before drawing any conclusions about the efficacy of medicinal cannabis in the treatment of insomnia disorder.[15] ANZCA Faculty of Pain Medicine advises the scientific evidence for the efficacy of cannabinoids in the management of people with chronic non-cancer pain remains insufficient to justify endorsement of their clinical use.

- In the absence of high-quality RCTs, clinicians must balance patient expectations with the limited evidence available.

Regulation and access to medicinal cannabis

- Legislation in Australia and New Zealand allows for the supply of medicinal cannabis products that are non-smokeable, medicinal-grade products, with Australia limiting supply to pharmaceutical grade products. Currently Sativex (nabiximols) is approved for supply in Australia by the TGA and by Medsafe in New Zealand, as a treatment for multiple sclerosis. Also, in Australia, low dose cannabidiol products included on the Australian Register of Therapeutic Goods (ARTG) can be made available over the counter with pharmacist approval Given the developing evidence and political priorities in this area, regulations are subject to change.

- In Australia access to medicinal cannabis is through a clinical trial, or prescription can be made via special TGA pathways for unapproved medicines, either the Special Access Scheme (SAS) or the Authorised Prescriber (AP) pathway. RANZCP does not approve TGA applications. Unapproved medicinal cannabis products are placed into categories 1 – 5 depending on their active ingredient concentrations. Each state and territory also have different laws governing access, with state-based authorities required in some states. National Prescribing Service has developed resources.

- In New Zealand a Medicinal Cannabis Scheme is administered by the Medicinal Cannabis Agency. Any medical doctor in New Zealand can prescribe unapproved medicinal cannabis products that meet the quality standard with no restrictions on the medical condition to be treated in line with prescription guidelines. [16] Further information is available from Best Practice Advocacy Centre New Zealand (bpac^{nz}).

Trends in use of medicinal cannabis Australia and New Zealand

- Australian data on medicinal cannabis prescribing demonstrates a considerable increase in the uptake of prescribed medicinal cannabis. [17] Authorised Prescriber data (2021-22) indicates that 24% of all patients, and 31% of new patients, were treated used THC products >98% (category 5 products). Across all applications, prescriptions for Schedule 8 medicinal cannabis products accounted for 78% of prescriptions. Under the SAS-B, chronic pain was the most prescribed condition (approx. 110,000 approved applications), followed by anxiety (70,000 approved applications). Prescribing data in New Zealand are not available.

- The regulatory framework appears to have attracted consumers with little or no prior illicit cannabis use (for medical or non-medical reasons), as well as transitioning a group of patients from illicit to prescribed medicinal cannabis products. [2]

Risks and side effects

Medical risks

- The are no studies that have evaluated the long-term side effects of using medicinal cannabis products. [4] However, medicinal cannabis products are found to increase the risk of short-term adverse effects such as disorientation, dizziness, euphoria, confusion, among others. [18]

- Some population groups may be particularly vulnerable to adverse events resulting from the use of medicinal cannabis products. Risk factors include age, pregnancy, mental health status and cognitive capacity, and cardiovascular disease. [19]

- The TGA advises that medicinal cannabis is not appropriate for people with a previous history of psychosis, or concurrent active mood or anxiety disorder. Several studies have linked illicit cannabis use to increased risks for chronic psychosis. [20, 21]

- Medicinal cannabis use in young people, particularly given the potential causal association between teenage use and later schizophrenia, urges particular caution. [22, 23] There is also evidence of potential negative impact – if used at high enough doses and for long enough - on certain aspects of neurocognitive functioning. [24] A large-sample study systematically investigating cannabis-associated psychotic symptoms leading to emergency medical treatment found that acute adverse reactions can occur and that some individuals are at a particular high risk (e.g., young users consuming potent forms of cannabis, those with mental health problems). [25]

- Despite extensive research into the nature of cannabis intoxication, evidence is lacking with regard to rates and correlates of medicinal cannabis-associated psychotic symptoms warranting clinical attention, such as events requiring emergency medical treatment. [25-27] In 2019-20 Australia recorded the highest ever rate of cannabinoid-related hospitalisations (including cannabis and synthetic cannabinoids) equating to an age-standardised rate of 26 hospitalisations per 100,000 people, mostly comprised a principal diagnosis of mental and behavioural disorder (92%). [28] These data do not separate trends in hospitalisations from recreational and medicinal cannabis users. It is unclear whether it is access to products, or the types of products that may be driving this association, with increased access to high potency extracts causing particular concern. [26]

- The risks of addiction associated with illicit cannabis use also suggest caution [29]. However, studies looking at the side-effect profile of medicinal cannabis products suggest they are relatively well tolerated [30] and an initial review of by the World Health Organization's Expert Committee on Drug Dependence found no associated public health risks or abuse potential. [31]

- Widespread smoking of prescribed medical cannabis products brings inherent health risks to lung and general health from smoking.

Professional practice and societal risks

- THC can impact on concentration and fine motor control, and have negative effects on driving ability or the use of machinery [22]. Side effects from medicinal cannabis products generally depend on the amount of THC in the product. Whilst THC blood levels associated with medicinal cannabis are often much lower than those associated with recreational cannabis use, the blood level associated with significant impairment is yet to be determined. The TGA recommends discussion between patient and doctor while under treatment with medicinal cannabis.

- Central to concerns of current use is that medicinal cannabis products are increasingly being prescribed for anxiety and other mental disorders when there are primary evidence-based treatments, such as cognitive behavioural therapy (CBT), which are not necessarily completed before a medicinal cannabis prescription. This risks disenfranchising people from seeking further help should the medicinal cannabis treatment not work. There is also a risk that prescribers are not asking key questions, including questions about past psychiatric conditions. A particular concern is psychosis vulnerability when prescribing the use of high potency THC products.

- There is risk of adverse effects associated with polypharmacy in general and with medicinal cannabis in particular when prescribed outside of psychiatry practice where patients are seeing psychiatrists and other prescribers concurrently. The high level of prescribing from online and

telehealth clinics presents a particular challenge, and requires diligent use of real time prescription monitoring systems. Such systems need to be designed to place shared responsibility on prescribers to better identify potential harm, and processes to communicate between healthcare providers.

- As with any medication, the side effects of specific medical cannabis products should be evaluated with the use of a risk–benefit analysis based on evidence of efficacy and safety. However, the relative paucity of firm data about efficacy and side effects in properly controlled trials which use specific combinations of particular cannabinoids for specific indications, make this challenging. [32]. Medicinal cannabis doses should be individually determined, with maximum doses understood, and interactions with other medications considered. [8, 32]

- Manufacturer and supplier direct to practice 'education' is a potential issue. A lack of research, or the promulgation of misinformation by companies with a vested interest supplying medicinal cannabis products, may result in doctors making uninformed decisions that are not based on evidence or best practice and may compromise safety. Direct-to-consumer advertising for medications makes this a particular risk in New Zealand.

- Medicinal cannabis products are expensive as they are not subsidised by governments. The cost is prohibitive for many individuals, resulting in them, or their carer, turning to illicit sources of cannabis. [22]

Using medicinal cannabis in practice

- Psychiatrists should take the decision to prescribe carefully and cautiously taking into account evidence for safety, quality and efficacy, and after detailed discussions of the potential benefits and harms of medicinal cannabis products with the person to be treated. Principles of good prescribing practice should be adhered to. Prescribing of medicinal cannabis products should only be done in a therapeutic environment.

- It is anticipated that psychiatrists will most frequently be asked to prescribe medicinal cannabis as a potential treatment for a mental illness, or alternatively asked by other medical doctors for their advice on prescribing medicinal cannabis for conditions for which there may be, or potential for, comorbid physical and mental disorders. Psychiatrists are well place to provide this advice as are very aware of the potential for misuse, dependence and side effects.

- The use of medicinal cannabis for the treatment of psychiatric conditions is considered a non-evidence based treatment. There remains insufficient evidence to provide guidance on the use of cannabinoids for treating mental disorders within a regulatory framework. [7] They should first be tested in randomised controlled trials and subjected to the same regulatory approval process as other prescription medications. [33]

The RANZCP therefore recommends that psychiatrists consider the following:

- It is preferred that the clinical use of medicinal cannabis, particularly for psychiatric disorders, should occur under robust clinical trials and case studies to test the efficacy, effectiveness and safety of long-term use of medicinal cannabis products, conducted under research trial conditions that include oversight by institutional research or clinical ethics committees with careful monitoring and reporting of outcomes.
- Psychiatrists who are considering the clinical use of medicinal cannabis outside of a research trial should:
    - be confident that medicinal cannabis is an appropriate option for the particular individual when other treatment options have failed
    - ensure that the patient is able and willing to consent to the treatment
    - ensure that clear information is provided to the patient, documented in the clinical notes, including an explanation that the use of medicinal cannabis is a novel treatment with detailed explanation of the current evidence and potential risks

- discuss the treatment with peers (preferably including a second opinion from a psychiatrist or other medical specialist with experience and expertise in the use of medicinal cannabis)
- ensure that medicines are accessed via appropriate processes in accordance with local laws
- acknowledge the complexity of co-morbidities and potential for risk when prescribing given the lack of evidence in this area may put people at greater risk of contraindications [34]
- base their decisions on evidence, clinical indicators, and best practice ensuring that medicinal cannabis has been subject to clinical trials to assure the efficacy, effectiveness and safety
- ensure the prescription of medicinal cannabis is subject to a regular review of progress, including monitoring for signs of aberrancy/diversion.
- exercise caution when treating any patient, being aware that they may have seen another prescriber and ensure real time prescription monitoring tools are used.
- give due consideration to the medico-legal risks involved
- where possible, seek institutional review by the medicines advisory committee or its equivalent
- where possible, seek institutional research or clinical ethics committee consideration
- utilise outcomes data from observational real-world studies to help address evidence gaps by contributing to clinical registries and by publishing clinical findings.

Where medicinal cannabis products are being prescribed 'off-label', see the RANZCP's guidance on off-label prescribing for further information.

Research and education

- Legislation to enable the use of medicinal cannabis should be backed up by an ongoing commitment to fund high quality research. In Australia research is largely being funded through philanthropy and the growing number of private companies with an interest in producing medicinal cannabis products for commercial profit. [22] In New Zealand, whilst the Medicinal Cannabis Scheme intends to monitor prescriptions and any adverse effects experienced will be monitored, there is no coordinated approach to research.

- A priority is to make available high-quality medicinal cannabis products and develop a scientific evidence-base for their use. There is a need for comprehensive monitoring systems and tracking of outcomes associated with medicinal cannabis. This should comprise careful scrutiny of any adverse effects both at an individual level as well as more broadly in society as messaging that cannabis is 'safe and good for you' could potentially encourage use, with potential detrimental effects, notably amongst young people whose brains are still developing and in whom drugs such as cannabis can have negative effects on cognition and mood and (in those with a vulnerability) psychosis. [22, 23]

- Impartial education for medical practitioners should be made available. Training must ensure potential prescribers are aware of the very limited evidence for efficacy, beyond certain forms of childhood epilepsy, and to understand the broader context of cannabis as part of the full range of medical treatments. This education should reflect the current state of knowledge and contextualise the use of medical cannabis products as a last-resort medication for specific categories of illness that should only be prescribed in rare circumstances after stringent legislative criteria are satisfied. [18]

- Public education further needs to reinforce the distinction between medicinal cannabis products and smokable and other illicit forms of cannabis, as well as between the different types of medicinal cannabis products available for use.

- Further research is needed into the benefits and longer-term impacts of medicinal cannabis, particularly the impact of increased prescription of all types of medicinal cannabis products use on transient and persistent psychotic syndromes, including hospitalisations.

Future regulatory considerations

- It is the view of the RANZCP that the regulation of medicinal cannabis products, where backed by sufficient evidence, should occur according to the same approval process as other new pharmaceuticals. The TGA in Australia and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) run well-established regulatory regimes which ensure that consumers have timely access to therapeutic advances with acceptable standards of effectiveness and safety, including consideration of the potential psychiatric implications for non-psychiatric conditions.

- As there are no restrictions on the medical conditions for which a prescriber can apply to use unapproved medicinal cannabis products, given the high rates of prescribing for anxiety in particular, RANZCP is concerned that patients are not receiving evidence-based treatment. Future refinements to legislation and treatment frameworks for medicinal cannabis should be considered in line with available evidence and harm minimisation strategies.

Summary

There is insufficient evidence to support medicinal cannabis as a treatment for anxiety and other mental disorders. Further research is required to ascertain the potential risks and benefits of the targeted use of medicinal cannabis. Further high-quality studies directly examining the effect of medicinal cannabis on treating mental disorders are needed. There is a role for psychiatrists in contributing to this research, as well as supporting other medical colleagues in providing advice on potential risks in using medicinal cannabis for other medical conditions. The RANZCP supports legislation that facilitates the research and, where backed by sufficient evidence, appropriate regulation of medical cannabis. These products should follow the same approval process as other new pharmaceuticals to ensure these standards are met before they are accessible.

As the evidence for the use of medicinal cannabis continues to evolve, this memorandum will be reviewed and revised.

Further reading

National Prescribing Service (Australia). Information and resources for consumers and health professionals.[Available from: https://www.nps.org.au/professionals/medicinal-cannabis-what-you-need-to-know]

Royal College of Psychiatrists (UK). Position Statement on cannabis-based medicinal products. November 2019.[Available from: https://www.rcpsych.ac.uk/docs/default-source/improving-care/better-mh-policy/position-statements/ps05_19.pdf?sfvrsn=2db968d3_2]

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Disclaimer

This information is intended to provide general guidance to practitioners, and should not be relied on as a substitute for proper assessment with respect to the merits of each case and the needs of the patient. The RANZCP endeavours to ensure that information is accurate and current at the time of preparation, but takes no responsibility for matters arising from changed circumstances, information or material that may have become subsequently available

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