



The Royal Australasian  
College of Physicians

This submission was prepared after the Victorian Law Reform Commission was assigned to review and report on options for changes to Victorian law to allow people to be treated with medicinal cannabis in exceptional circumstances.



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**The Royal Australasian College of Physicians (RACP)**

**Submission to the Victorian Law Review Commission on  
Medicinal Cannabis**

**April 2015**

- 1. Which of the following considerations should determine whether there are exceptional circumstances for medicinal cannabis to be made available to a patient:**
  - a) the circumstances of the patient**
  - b) the state of clinical knowledge about the efficacy or potential efficacy of using cannabis in treating the patient's condition**
  - c) both of the above?**

The RACP supports (c). Both the circumstances of the patient and the level of clinical knowledge about the efficacy of using cannabis for the patient's particular condition should be considered before medicinal cannabis is made available to any patient. The RACP recommends the term "be made available" is clearly defined to distinguish between the prescription and supply of cannabis (or both) and remove any legal consequences associated with use in exceptional circumstances.

**2. For what conditions is there sufficient knowledge of the therapeutic benefits, dangers, risks and side effects of cannabis to justify allowing sufferers to use it lawfully in Victoria?**

The RACP operates from an evidence based position. As such it considers that the majority of the trials that have taken place on this issue have been small and weak and have not been tested against standards of care. Randomised controlled trials are required to establish the efficacy and benefits of treating particular conditions with medicinal cannabis and evidence of any harm that may arise as side effects. Unfortunately, the current legislation, regulatory frameworks and conventions have not kept pace with this scientific progress. For example, the *Single Narcotic Drug Convention 1967* was established prior to the discovery of the endocannabinoid system that comprises specific cannabinoid receptors to regulate numerous physiological processes.<sup>1</sup> The convention is now a hindrance to the science and restricts the opportunity for research into the area of medicinal cannabis to validate anecdotal claims made of its benefits.

With respect to specific conditions, the RACP can only answer this question for those conditions on which it has received feedback from Fellows who are experts in that particular specialty.

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<sup>1</sup> Robson, P.J., Therapeutic potential of cannabinoid medicines, *Drug Test. Analysis*, 2014: 6, 24–30

**Palliative Care:** In the case of terminally ill patients, the use of medicinal cannabis (if the patient wishes to trial its use) most likely holds limited potential for damage and can always be ceased if there is no useful response. The RACP acknowledges there are many anecdotes where the use of cannabinoids have greatly benefited terminal patients without the associated side effects that opioid use cause.<sup>2</sup> Vulnerable populations such as the elderly should be thoroughly counselled on its potential risks and benefits and some patient groups such as those with pre-existing psychiatric disease may not be suitable. The RACP would also point to the risk of a push to make cannabinoids more accessible for non-terminal illnesses, where the risk-benefit analysis will be very different.

**Paediatric epilepsy:** There is currently insufficient evidence of efficacy to justify medical prescription of cannabis outside of a randomised, placebo-controlled trial, and there is insufficient current evidence of long-term safety to allow the same. Notwithstanding this, the circumstances of children with drug-resistant epilepsy may be such that the risk of harm from cannabis is thought or judged to be minor in comparison to the risk of ongoing seizures. In those cases it seems reasonable to define it as an “exceptional circumstance” and attempt a trial of treatment with cannabis in some form, depending on the availability of and the form of the product or substance and the legal framework in which it is to be obtained and consumed.

The RACP is aware that GW pharmaceuticals is currently undertaking research on the effectiveness of cannabidiol (CBD) – one of many active cannabinoids in cannabis – purified and formulated as Epidiolex, in the treatment of two orphan indication syndromes: Dravet Syndrome and Lennox-Gastaut Syndrome. The results of these trials will establish some level of evidence to support the use of CBD in the treatment of these two conditions and perhaps other forms of paediatric epilepsy refractory to current treatments

**Multiple Sclerosis:** Many multiple sclerosis specialists believe there is sufficient scientific evidence to develop guidelines to trial the medical prescription of cannabinoid products (Nabiximols - Sativex) for the treatment of spasticity in some patients with multiple sclerosis.<sup>3</sup> Muscle spasticity is a significant problem for many people living with multiple sclerosis and therapeutic options are currently limited. The drug was approved for this use in Australia by the TGA in 2012 and also the regulatory authorities in the United Kingdom, Spain and Canada. But despite the TGA listing Sativex, it is still not available for use in Australia because a change to the poisons schedule is required before Sativex can be prescribed by neurologists. In addition, the RACP acknowledges that in 2013 the Pharmaceutical Benefits Advisory Committee rejected a submission to subsidise Sativex, on the basis that trials did not demonstrate better efficacy than existing options.<sup>4</sup>

**3. What special considerations, if any, justify access to medicinal cannabis for:**  
**a) patients who are under 18 years of age**  
**b) patients who lack capacity by reason of age or another disability (other than youth) to consent to using medicinal cannabis?**

For both situations referred to above, the first consideration to justify access to medicinal cannabis is that there is a medical indication for prescribing it and that administration of medicinal cannabis is in the child’s (or disabled person’s) best interest. A plan for monitoring adverse effects and benefits should also be in place. If these points are considered, no further special consideration should be required for non-*Gillick* competent patients. The same considerations should apply as to any medical treatment or non-medical therapy given

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<sup>2</sup> Regulator of Medicinal Cannabis Bill 2014, Legal and Constitutional Affairs Legislation Committee Senate hearing, Sydney, 31 March 2015.

<sup>3</sup> Zajicek, J.P. and Apostu, V.I., Role of cannabinoids in Multiple Sclerosis, *CNS Drugs*, 2011: 25(3), 197-201

<sup>4</sup> <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2014-07>

or facilitated by the legal guardian of the minor and consent therefore would be within the bounds of parental responsibilities as per *Re Sean and Russell (Special Medical Procedures)* [2010] FamCA 948 [75].

**4. On which of the following should the law creating a medicinal cannabis scheme base a person's eligibility to use medicinal cannabis:**

- a) a list of medical conditions
- b) a list of symptoms
- c) a list of symptoms arising from certain medical conditions
- d) evidence that all reasonable conventional treatments have been tried and failed?

The RACP recommends (c) to determine a person's eligibility to use medicinal cannabis. As an example, in the case of epileptic seizures, the indication would be seizures (the symptom) due to or arising from drug-resistant epilepsy (the medical condition).<sup>5</sup> Not all epilepsy variants are drug-resistant vetoing option (a). In many cases of apparent drug-resistance, the epilepsy diagnosis is incorrect after further assessment or the medication chosen in the first two instances is inappropriate which discredits option (d). Furthermore, many patients regarded as drug-resistant may be appropriate candidates for potentially curative epilepsy surgery. Therefore, the diagnosis of drug-resistant epilepsy should be made only after comprehensive evaluation that will usually include video-EEG monitoring of seizures and consultation by a neurologist with special expertise in epilepsy. It is not appropriate that all reasonable conventional treatments have failed before a person is eligible to use medicinal cannabis; this is not a requirement for antiepileptic drug trials or for potentially curative epilepsy surgery.

A symptom list alone is not appropriate to determine a person's eligibility because symptoms can be common across multiple conditions therefore (b) above is not a valid option. For example, not all seizures are epileptic, some seizures are symptomatic of other remediable conditions such as alcohol abuse or electrolyte imbalance, therefore a thorough evaluation of the patient, condition and treatment options are required.

The situation for multiple sclerosis is similar and (c) is appropriate. Some studies have shown improvements in symptoms associated with multiple sclerosis when treated with cannabinoids with relatively few adverse effects.<sup>6</sup> Some multiple sclerosis specialists feel it would be a valid treatment inclusion to trial to treat some symptoms of multiple sclerosis when other therapeutics are ineffective.

**5. Should there be a way to allow for special cases where a person who is otherwise ineligible may use medicinal cannabis? If so, what should that be?**

The RACP cannot identify any situations where a person who is otherwise ineligible should be allowed to use medicinal cannabis as a special case, unless it is in a properly designed clinical trial for which they meet the subject criteria.

**6. If Victoria acted through a state agency, in what circumstances would it be legally entitled to establish a medicinal cannabis scheme which manufactured cannabis products without breaching the terms of the Therapeutic Drugs Act 1989 (Cth) or the Narcotic Drugs Act 1967 (Cth)?**

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<sup>5</sup> According to the *International League Against Epilepsy*, 'drug-resistant epilepsy' is defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom.

<sup>6</sup> Zajicek, J.P. and Apostu, V.I., Role of cannabinoids in Multiple Sclerosis, *CNS Drugs*, 2011: 25(3), 197-201

This question is outside the RACP's scope of expertise and requires a legal perspective.

**7. Are the regulatory objectives identified by the Commission appropriate? What changes, if any, would you make to them?**

The RACP at this stage has no changes to suggest to the Commission's regulatory objectives as it is limited to allowing access to medicinal cannabis in exceptional circumstances.

**8. Would the creation of a defence to prosecution for authorised patients and carers in possession of small amounts of dried cannabis or cannabis products be an adequate way of providing for people to be treated with medicinal cannabis in exceptional circumstances?**

A defence to prosecution would allow carers to administer cannabis without fear of prosecution. However it would not ensure the safety or reliability of the composition of the product consumed.

The RACP recommends the cannabis and cannabinoid products allowed to be used for medical purposes are clearly defined and that provisions are made in the legislation for other products for the purposes of clinical trials. This is to discourage persons from using dried cannabis via inhalation that carries proven health risks to both themselves and others around them.

**9. What mechanism should Victoria use to regulate the cultivation of medicinal cannabis?**

The RACP recently provided a submission on the *Regulator of Medicinal Cannabis Bill (2014)* that was debated by the Legal and Constitutional Affairs Legislation Committee in March 2015. This Bill seeks to form regulations to govern the cultivation of medicinal cannabis to comply with the United Nations *Single Convention on Narcotic Drugs 1961* and is relevant to the cultivation of medicinal cannabis.

The RACP did not support the Bill because it covers activities beyond the scope of the *Therapeutic Goods Act 1989* (the TGA) and sections are inadequate compared to the functions of the TGA to monitor and regulate the quality and safety of medicinal cannabis products. The RACP therefore recommends it is more appropriate for all medicinal cannabis products to be registered and monitored under the TGA. The TGA is an experienced body with a proven history of regulating medicines of a standard quality. The RACP cannot comment on legal structures to allow the cultivation of medicinal cannabis products.

**10. What approach, or approaches, should Victoria take to regulating how medicinal cannabis is processed and distributed?**

The RACP does not have the expertise to comment on how medicinal cannabis should be processed and distributed.

**11. How should the Victorian medicinal cannabis scheme interact with the national arrangements for the control of therapeutic products under therapeutic goods legislation and narcotic drugs legislation?**

The Victorian medicinal cannabis scheme could be established to allow prescription of therapeutics approved by the TGA. This would allow products such as Sativex that is already listed by the TGA, to be prescribed. (See question 2 for further details.)

It is anticipated if the Victorian medicine cannabis scheme comes into effect, a number of patients will travel to Victoria for treatment. Under the Drugs Poisons and Controlled Substances Act 1981 and Health Professions Registration Act 2005, a medical practitioner registered by the Medical Practitioners Board of Victoria but practising in another state will be able to prescribe medicinal cannabis.<sup>7</sup> Pharmacies in other states and territories will not be able to act on prescriptions though unless administration of pharmacotherapy to a specific patient has been authorised in that jurisdiction.

## **12. What responsibilities should be given to health practitioners in authorising a patient's use of medicinal cannabis?**

Responsibilities given to health practitioners authorising a patient's use of medicinal cannabis should be aligned with the regulations and policies for prescribing Schedule 8 therapeutics under the Drugs Poisons and Controlled Substances Act 1981 and Health Professions Registration Act 2005.

It is unacceptable for a doctor to be asked to authorise a patient's use of or prescribe a substance of unknown composition and uncertain clinical effects. Therefore this would firstly depend on the type of medicinal cannabis being referred to and will require acceptable formulations to be clearly defined.

In the absence of a reliable supply of cannabis products of known and certified composition, the doctor's responsibilities must be confined to certification of a person's eligibility as per question 4 and the monitoring of drug interactions and adverse effects.

If a reliable and legal supply of a purified form of medicinal cannabis is established in Victoria, but an absence of trial data concerning efficacy, safety and dosing information persists, the doctor's role in prescribing medicinal cannabis should be as per the conduct of a clinical trial, whether this be an adequately powered controlled trial of a number of patients, or a number of trials undertaken for individual patients. In any case, the patient and / or carer must be fully informed of the proposed medicinal cannabis product including potential side effects of cannabis use and the current knowledge status. They must consent to the trial and be aware that the use of cannabis is experimental.

If the trial is intended to produce results to be disseminated in the medical literature, then the trial must be conducted in an ethically approved and regulated framework as for all investigational product trials.

If the product is already registered for this indication outside of Australia then the TGA Special Access Scheme would be appropriate and it could be prescribed without a research infrastructure.

## **13. Who should have the authority to assess whether a patient is an appropriate candidate to be treated with medicinal cannabis:**

- a) all registered medical practitioners**
- b) certain designated specialist medical practitioners**
- c) registered health practitioners who have prescribing entitlements**
- d) a subset of these?**

The RACP recommends (c) that registered health practitioners who have prescribing entitlements should have the authority to assess a patient for appropriateness to be treated

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<sup>7</sup> Interstate prescriptions for Schedule 8 poisons in Victoria, Department of Health, Victoria, 2012  
<http://docs.health.vic.gov.au/docs/doc/Interstate-prescriptions-for-Schedule-8-poisons-in-Victoria>

with medicinal cannabis. It is recommended the TGA provide a register of approved prescribers for medicinal cannabis similar to its current practice for various cancer drugs for which prescribing rights are limited to recognised oncologists specialising in that field.

Authority should be further restricted to only physicians with special expertise in the condition it is being referred to treat, e.g. paediatric neurologists for childhood epilepsy or adult neurologists for multiple sclerosis. This restriction is proposed because as identified in the Issues Paper, there is a long list of proposed conditions for which medicinal cannabis has been suggested. This would avoid a sudden influx of prescriptions that may be otherwise inappropriate and prior to other treatment options being explored.

For example, to prescribe medicinal cannabis in paediatric epilepsy, the eligibility criteria above (see question 4) necessitate that the assessment be made by a physician with special expertise of the condition such as a paediatric neurologist and not by a paediatrician or adult neurologist.

#### **14. What requirements, restrictions, guidance or other assistance should health practitioners be given in monitoring a patient's use of medicinal cannabis?**

Restrictions should be placed on prescription frequency of medicinal cannabis to prevent overuse, misuse and misappropriation of the therapeutic.

The state government should recognise that the commencement of a framework for medicinal cannabis use will create a demand within the public health system. Therefore, clear guidelines will need to be developed on patient eligibility, prescription restrictions, and prescribing authority to avoid inappropriate use and active long-term monitoring of the patient for efficacy and adverse effects. Providing guidelines for health professionals will ensure they know what is expected of the patient or carer and that the patient is fully aware of medicinal cannabis's limitations and potential side effects.

#### **15. What additional restrictions or requirements, if any, should apply to patients who are vulnerable by reason of age or lack of capacity, so as to provide adequate protection for their welfare?**

As well as fulfilling the criteria in question 3 to ensure the treatment is in the patient's best interests, the RACP suggests vulnerable patients and / or their carers should be required to demonstrate that cannabinoid therapeutics are in the possession of the patient. This would be in order to protect a vulnerable patient from their therapeutics being misappropriated.

#### **16. In what form(s) should medicinal cannabis be permitted to be supplied and used?**

The delivery of medicinal cannabis via smoking raises obvious health concerns for the user as well as accidental ingestion by others through passive smoking. Therefore smoking is not a recommended form of delivery.

It is recommended permitted forms of medicinal cannabis should be limited to cannabis products that have been tested and approved through the TGA.

The RACP suggests that if medicinal cannabis is introduced, it should be administered and supervised by clinical health networks after rigorous consultation with those networks, and funding should be made available to monitor, audit and conduct clinical trials to reassess its efficacy.

**17. In what ways could Victoria's medicinal cannabis scheme keep pace with, and contribute to, clinical research into the therapeutic uses of cannabis and other changes in scientific knowledge, medical practices and technology?**

The RACP's position on medicinal cannabis is that its use should be evidence based. However for some conditions such as multiple sclerosis, it is felt by some specialists in this area that there is sufficient evidence of benefit to support the use of cannabinoids in spasticity. At present the evidence for the efficacy and evidence of various spasticity treatments (not only cannabinoids) is poor,<sup>8</sup> so further research is required.

The RACP advocates for further clinical trials to develop an evidence base for the safety and efficacy of medicinal cannabis to guide its therapeutic use. This is the primary role that the RACP proposes Victoria's medicinal cannabis scheme takes to contribute to the currently available scientific knowledge of medicinal cannabis. Commenting on the appropriate legal structure to allow the supply of medicinal cannabis is beyond the RACP's scope of expertise, but it does support the introduction of a mechanism to allow a legal supply for the purposes of conducting clinical trials.

For further information or to discuss this issue further please contact Veronica Vogel, Policy Officer, [REDACTED]

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<sup>8</sup> Zajicek, J.P. and Apostu, V.I., Role of cannabinoids in Multiple Sclerosis, *CNS Drugs*, 2011: 25(3), 197-201