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The Royal Australasian College of Physicians

The Royal Australasian College of Physicians (RACP)

Submission to Queensland Health on
The Public Health (Medicinal Cannabis) Amendment Bill 2016
March 2016

1. Do you support the use of medicinal cannabis in Queensland?

The Royal Australasian College of Physicians (RACP) supports the use of medicinal cannabis in clinical trials, to develop an evidence base for the use of medicinal cannabis. This is in light of the lack of evidence surrounding its use, methods of administration, form and dosage, and concern for safety in vulnerable patient groups.

There are a limited number of medical conditions for which there is sufficient evidence on the use of medicinal cannabis, and therefore use of an unlicensed product may be warranted. Comments on the four medical conditions identified in the Bill are included below:

Medical condition	Comments
1. **Severe muscle spasms or pain resulting from multiple sclerosis**	There is sufficient evidence to support medicinal cannabis use for this condition, and indeed the medication nabiximols (Sativex®) is licensed for this indication in Australia.[1] Other THC/CBD products of similar composition may be appropriately considered.
2. **Severe nausea, severe vomiting or severe wasting resulting from cancer or HIV/AIDS (or the treatment thereof)**	Whilst medications such as dronabinol and nabilone are licensed internationally for this indication, many of the trials were conducted many years ago and the safety and efficacy of medical cannabis products compared with contemporary treatment approaches remain unclear. Regarding HIV/AIDS, advancements in retroviral treatment means its use for cachexia is uncommon. Nevertheless, where a patient is not responding to conventional 'best practice' therapies, a test of medicinal

[1] Australian Government, *Australian Register of Therapeutic Goods – ARTG ID 181978,* Therapeutic Goods Administration. Accessed 17 March 2016 at https://www.tga.gov.au/artg/artg-id-181978.

	cannabis may be warranted.
3. Severe seizures resulting from epileptic conditions where other treatment options have not proved effective or have generated intolerable side effects	The evidence for medicinal cannabis (specifically CBD) is promising, yet still emerging. We note recent announcements regarding the positive findings of CBD trials in children with Dravet's condition, and we await the impending peer review publication of these trials.
4. Palliative care, particularly related to terminal health conditions.	Similarly, nabilone and dronabinol have been licensed internationally for management of cachexia and related suffering in palliative care patients; and safety and efficacy may be extrapolated to other medicinal cannabis products of similar composition.

2. What, if any, concerns do you have about the use of medicinal cannabis in Queensland?

The RACP does hold concerns about the proposed use of medicinal cannabis in Queensland. The first concern is due to the lack of evidence regarding its efficacy for treatment of many conditions, especially in comparison to other rigorously tested therapeutics already available. The RACP therefore supports clinical trials to develop an evidence base to support the effective and safe use of medicinal cannabis.

The lack of approved medicinal cannabis therapeutics is also a cause of concern as this means there are no guidelines available for physicians. A recent survey of Victorian RACP members indicated that physicians would like guidelines and training in the use of medicinal cannabis to determine appropriate dosage, and understand associated side effects and how to monitor patients on medicinal cannabis.

Managing the risk of harm and minimising opportunities for medicinal cannabis misuse is another concern expressed by members of the RACP. This includes concerns about the appropriateness of using medicinal cannabis in patients with addiction and mental health issues.

Lastly, patient expectations of the effectiveness of medicinal cannabis appear to be inflated due to media promotion. This is a concern when there are generally other more appropriate and clinically proven therapeutics that should be tried before medicinal cannabis, and accurate information on the risk and side effects is not available.

3. If you have any concerns about the use of medicinal cannabis in Queensland, how might these be managed or prevented?

Limiting medicinal cannabis use to clinical trials would allow a rigorous evidence base to be established. This would include data on whether treatment with medicinal cannabis can be integrated into the patient's existing medical treatment, and outcome comparisons with alternative treatments suitable for the patient's medical condition.

The proposed Bill identifies a range of checks and balances regarding which patients can be treated, which medical cannabis products can be used, which prescribers can prescribe, and the process for approving dispensing pharmacies.

However, consideration should be given to the optimal number of approved prescribers, and ensuring that they have been appropriately trained and can be audited.

Providing training to physicians and guidelines on medicinal cannabis pharmacology and prescribing will support the safe administration and management of patients using medicinal cannabis. This aligns with the factors the chief executive will consider when deciding on applications, as outlined in the proposed regulatory framework, of:

- *the suitability of the patient to be treated with medicinal cannabis*
- *the patient's medical condition*
- *the form and dosage of the medicinal cannabis proposed by the medical practitioner to treat the patient*

It is recommended that consumer factsheets and/or a public information campaign on medicinal cannabis be developed to inform patients and their carers about medicinal cannabis, and to manage their expectations.

4. What, if any, special provision should be made for treating patients who are under 18 years of age?

In treating patients under 18 years, the first consideration is whether there is a medical indication for prescribing and whether administration of medicinal cannabis is in the child's best interests. 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 or facilitated by the legal guardian of the minor. There are already robust state, national, and international laws in place specifying the rights of children.

Apart from the above requirements, paediatric neurologists have expressed discomfort about medicinal cannabis being administered to children outside of well-designed paediatric clinical trials with Human Research Ethics Committees approval and adequate monitoring. This is in the absence of efficacy and safety data.

5. What, if any, special provision should be made for treating patients with impaired capacity to consent to treatment?

The same considerations should apply as to any medical treatment or non-medical therapy given or facilitated by the legal guardian of the patient with impaired capacity. There is already a regulatory framework in place in Queensland for guardianship for adults with impaired capacity. The first consideration is that there is evidence that the person does not have capacity to consent. Then, to justify access to medicinal cannabis, there must be a medical indication for prescribing it and confirmation that administration of medicinal cannabis will be to the patient's benefit.

It should be noted that the use of medicinal cannabis most likely qualifies as a special health care matter under the Queensland guardianship regulations. Medical procedures that are considered special health care matters include "participation by the adult in special medical research or experimental health care". This falls outside the boundaries of ordinary health care a guardian can consent to and requires the Queensland Civil and Administrative Tribunal or the Supreme Court to consent to the procedure.

6. What, if any, special provision should be made for treating patients in rural or remote areas?

It is unreasonable to expect sick patients or their carers to travel long distances to access medicinal cannabis if they are eligible. Services such as the Medical Specialist Outreach Assistance Program (MSOAP), telehealth and the Rural Health Services Directory promote health equality by allowing rural and remote patients to access specialist care; and medicinal cannabis should be no different.[2] Eligible patients should still be able to access medicinal cannabis through these avenues. Rural and remote patients could then potentially be monitored through a shared care arrangement after an application has been approved by a relevant specialist. It is assumed the Expert Advisory Panel will identify and make recommendations regarding the relevant expertise of medical practitioners involved in treatment – including any shared care arrangements.

Medicinal cannabis could be delivered to their closest hospital pharmacy to allow eligible patients to access it.

Additional comments

Physician and General Practitioner roles

The RACP is concerned that the proposed framework and its definitions allow for approval of any medical practitioner to prescribe medicinal cannabis to patients, where the medical practitioner may be a general practitioner or specialist medical practitioner.

The RACP recommends approval should be restricted to physicians with special expertise in the condition being treated, e.g. paediatric neurologists for childhood epilepsy or adult neurologists for multiple sclerosis. In the course of the RACP consultation, paediatric neurologists advised that in cases of paediatric epilepsy, general practitioners are usually not comfortable monitoring or prescribing for other aspects of paediatric epilepsy management, especially in children with refractory epilepsy who are often on multiple anticonvulsants.

Where regular access to a relevant specialist is not possible (e.g. due to geography), then treatment with medical cannabis should be conducted in a well-documented 'shared care' arrangement between specialist and GP, and the specialist should make the application for approval. Patients with one of the proposed conditions would be under the care of a

[2] Queensland Government, *Accessing specialists in rural and remote areas,* 2016. Accessed 17 March 2016 at https://www.qld.gov.au/health/services/specialists/rural-remote/index.html

specialist who will be better positioned to adjust the patient's treatment regimen and judge if medicinal cannabis is a viable treatment option than a general practitioner.

The RACP notes the stipulation in the proposed regulatory framework that the chief executive may consider "..the suitability of the medical practitioner to be granted a medicinal cannabis approval." We assume that it will be the role of the Expert Panel to identify and make recommendations regarding the relevant expertise of medical practitioners involved in treatment – including any shared care arrangements.

The above measures are recommended to help prevent a sudden influx of prescriptions that may be inappropriate and at the expense of other suitable treatment options being explored.

Application approvals
The RACP notes that approval is fixed to the form, dosage and dispensing intervals of the medicinal cannabis product. This does not allow for dosage adjustments that are sometimes required when monitoring patients on therapeutics, especially in this case as the listed agents do not have established dosage ranges. The proposed process will be unduly cumbersome as each application may take up to 90 days to be processed. A more timely approval process (e.g. 4-6 weeks) should be sought, particularly given the severe nature of the medical conditions being treated.

Expert advisory panel
The RACP is pleased to note that an expert advisory panel will appointed, but recommends at least one physician from a specialty relating to the eligible conditions, is included on the expert advisory panel. If this is not practical, an independent specialist should be consulted for individual cases. A decision on whether a patient should receive medicinal cannabis for a particular medical problem should be made by a panel of medical specialists. Other non-medical matters should be referred to relevant members of the expert advisory panel.

Review of the legislation
As the Bill identifies specific conditions eligible to be treated, it is recommended the legislation is reviewed at 2-3 yearly intervals or as advised by the expert advisory panel. This would allow consideration of changes to the evidence base and alignment with practice guidelines for specific conditions.

For further information or to discuss this issue further please contact V[redacted]