The regulatory framework for medicinal use of cannabis products

Position Statement – 2019 update

Position

The process of prescribing medicinal cannabis products in Australia remains highly bureaucratic, time consuming and expensive for patients, and differs significantly in every state and territory. A consistent national regulatory framework for prescribing medicinal cannabis products should be developed, which includes:

- a user-friendly, single-step approval process that acts as a submission portal to **all** relevant authorities (ie federal and state/territory regulators)
- efficient and timely processing of requests
- legislative consistency between federal and state/territory governments around access to medicinal cannabis products
- education and training around evidence-based indications, regulatory requirements and prescribing processes of medicinal cannabis products
- a process where GPs should be treated like any other specialist, and have the autonomy to determine when it is appropriate to prescribe to eligible patients
- a consideration of introduction of approved medicinal cannabis products on real-time prescribing systems.

Background

The intent of the February 2016 amendments[1] to the *Narcotic Drugs Act 1967*[2] was to allow the supply of medicinal cannabis products for the management of patients with certain medical conditions. Although further research is warranted and necessary in order to clarify the residual uncertainties of the relative efficacy and safety of various medical cannabis products, medicinal cannabis products can now be prescribed in Australia.

The Royal Australian College of General Practitioners (RACGP) updated its position statement in early 2019, which outlined the position on prescribing medicinal cannabis products in general practice, the challenges general practitioners (GPs) face, and the evidence base at that time. While the regulatory and prescribing regime must be robust to ensure only appropriate clinical access within the confines of the legislation, the prescribing process should be fit for purpose.

Approval process

The types of medicinal cannabis products that can be prescribed and the medical conditions that may warrant prescribing are not stipulated in legislation, and are generally considered on a case-by-case basis. Importantly, depending on their content, medicinal cannabis products are scheduled and managed differently under the Schedule of Medicines and Poisons (Poisons Standards) in each state and territory. Adding to the complexity, the legal requirements for prescribing medicinal cannabis products vary depending on how the individual product is scheduled in the jurisdiction.

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With the exception of Tasmania, all states and territories medicinal cannabis product prescribers can now submit a single application to satisfy both Commonwealth and state/territory-specific requirements to prescribe unapproved medicinal cannabis products. It is envisaged that when all necessary information has been received, a decision will be made within 48 hours that contains both Commonwealth and state/territory-specific approvals.

The constant changes to, and complexities with, state and territory legislation around accessing medicinal cannabis products are significant barriers for GPs (Table 1).

Table 1. Prescribing medicinal cannabis products (SAS) – Jurisdictional differences*

Jurisdiction	Authorised prescriber	Jurisdiction-specific information	Jurisdiction-specific condition
Australian Capital Territory (ACT)	• Specialists only • General practitioners with specialist support (SAS Category B only)	• Concurrent application to the TGA and ACT Health • ACT Health will evaluate application against *ACT Controlled Medicines Prescribing Standards*	Medicinal cannabis products only for: • spasticity in multiple sclerosis • nausea and vomiting from cancer chemotherapy • pain and anxiety related to active malignancy from a life limiting disease with a prognosis of ≤12 months • refractory paediatric epilepsy
New South Wales (NSW)	• Specialists only • General practitioners with specialist support (SAS Category B only)	TGA's Special Access Scheme Application NSW Health application required where prescribing or supplying for a: • drug dependent person • clinical trial • child aged <16 years	Medical conditions where there is evidence to support its therapeutic use
Northern Territory (NT)	• Specialists and general practitioners can apply to be a single-patient prescriber	Concurrent application under the TGA's Special Access Scheme Application **Department of Health** • Schedule 8 products require notification to the NT Chief Health Officer for treatment >2 months • Prescriptions for all Schedule 8 products (eg medicinal cannabis) must be written by a prescriber in the NT	Medical conditions where there is evidence to support its therapeutic use

Jurisdiction	Authorised prescriber	Jurisdiction-specific information	Jurisdiction-specific condition
Queensland	• Specialists and general practitioners can apply to be a single-patient prescriber	TGA's Special Access Scheme Application Queensland Health application required where prescribing or supplying for a: • drug dependent person Medicinal cannabis products **without** Queensland Health approval: • Schedule 4 – cannabidiol (CBD) only • Schedule 8 – products containing tetrahydrocannabinol (THC)	Medical conditions where there is evidence to support its therapeutic use
South Australia (SA)	• Specialists only • General practitioners (specialist support may be required)	Concurrent application under the TGA's Special Access Scheme Application **SA Health** All Schedule 8 drugs: • Apply for a s18A *Controlled Substances Act 1984* authority Medicinal cannabis products **without** SA Health approval: • Schedule 4 cannabidiol (CBD) medicine • Patients aged <70 years • Patients with life expectancy <12 months Authority required for: • Treatment >2 months or expected to be >2 months • drug dependent person	Medical conditions where there is evidence to support its therapeutic use
Tasmania	• Specialists only	• Commonwealth approval process – TGA's Special Access Scheme Application • State approval process – Delegate of the secretary of the Tasmanian Department of Health • Schedule 8 medicines evaluated under Section 59E of the *Poisons Act 1971* • Schedule 4 cannabidiol evaluated under Regulation 87 of the *Poisons Regulations 2018*	May be prescribed to treat any condition

Jurisdiction	Authorised prescriber	Jurisdiction-specific information	Jurisdiction-specific condition
Victoria	• Registered medical practitioner	Concurrent application under the TGA's Special Access Scheme Application **Victoria Health** Medicinal cannabis products **without** Victoria Health approval: • Schedule 4 medicine Schedule 8 medicinal cannabis products – Schedule 8 Treatment Permit under *Victorian Drugs Poisons and Controlled Substances Act*	Medical conditions where there is evidence to support its therapeutic use
Western Australia (WA)	• Authorised specialists only	TGA's Special Access Scheme Application Medicinal cannabis products **without** WA Department of Health approval: • Schedule 4 medicines	Medical conditions where there is evidence to support its therapeutic use

Prescribing medicinal cannabis products

In general, GPs can only gain access to medicinal cannabis products through the Special Access Scheme (SAS), often with the support of a specialist treating the medical condition. GPs generally cannot access the Authorised Prescriber Scheme (APS).[3] GPs who wish to obtain Human Research Ethics Committee (HREC) endorsement as an Authorised Prescriber should first contact a clinical HREC (ie hospital HREC). If a GP is unable to access a hospital HREC, then it is recommended that they seek endorsement from an appropriate HREC.

GPs making an application through the SAS must be able to demonstrate evidence of the benefits of the proposed treatment with a medicinal cannabis product, and that all other treatment options have failed. A treatment plan and ongoing monitoring plan must also accompany the application. SAS approvals are generally valid for 12 months, after which the application process must be repeated for treatment continuity.[3]

Any system of prescribing should recognise that GPs are specialists, and therefore should have the autonomy to determine when it is appropriate to prescribe medicinal cannabis products to eligible patients.

Recommendations: Approval process

As evident by the complexities of prescribing medicinal cannabis products noted above, the RACGP advocates for the simplification and streamlining of regulatory processes for eligible patients to access medicinal cannabis products. This has the potential to ensure patient safety and reduce variation because of different jurisdictional processes. In particular:

- The administrative requirements of accessing medicinal cannabis products should not be unnecessarily duplicated. The introduction of a user-friendly, single-step approval process that acts as a submission portal to **all** relevant authorities (ie federal and state/territory regulators) would help to facilitate this goal.
- Patients for whom accessing medicinal cannabis products is indicated often have chronic and debilitating conditions, and helping to ease these patients' pain in a timely manner is essential. Processing requests for access to medicinal cannabis products on all levels of government therefore need to be timely and efficient.
- There needs to be legislative consistency between federal and state/territory governments to remove the legal complexities around prescribing medicinal cannabis products, and so there is clear understanding of the GP's legal obligations.

Education

As with any emerging treatment available on the market, especially those with limited evidence for efficacy and safety, GPs who consider prescribing these drugs need to be able to readily access evidenced-based information and educational material. Evidence-based clinical resources and education for prescribing medicinal cannabis products are essential for patient safety and uptake. While Australian and international guidelines are available,[3,4,5] there is a need for the ongoing development of best practice guidelines. GPs should be provided with resources on the legislative and clinical aspects of prescribing medicinal cannabis products, as well as guidance on clear and proper governance processes on prescribing medicinal cannabis products.

Patient education is also crucial.

GPs are specialists, and those who wish to prescribe medicinal cannabis products should be treated like any other specialist, and have the autonomy to determine when it is appropriate to prescribe to eligible patients.

Real-time prescribing

An effective real-time prescribing system has the ability to save lives and protect the community by identifying patients who are at risk of misusing prescription medicine. The RACGP believes that as real-time prescribing systems continue to be rolled out across states and territories, they have the potential to be used to reduce and mitigate the risk of misuse or diversion of medicinal cannabis products.

Conclusion

The RACGP encourages the Council of Australian Governments (COAG) Health Council (CHC) to explore the implementation of the RACGP's recommendations. A consistent national regulatory framework for prescribing medicinal cannabis products should be developed, which facilitates access when clinically appropriate, and reduces the bureaucratic, time consuming and expensive process doctors and patients currently face when trying to access medicinal cannabis products. It will help ensure that patient's welfare is at the centre of this difficult and rapidly evolving area of medicine.

References

[1] Commonwealth of Australia. Narcotic Drugs Legislation Amendment Act 2016. Canberra: Commonwealth of Australia, 2016.
[2] Commonwealth of Australia. Narcotic Drugs Act 1967. Canberra: Commonwealth of Australia, 1967.

[3] Therapeutic Goods Administration. Guidance for the use of medicinal cannabis in Australia: Overview. Canberra: TGA, 2017. Available at www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-overview [Accessed 5 March 2018].
[4] Queensland Health. Clinical guidance for the use of medicinal cannabis products in Queensland. Brisbane: Queensland Health, 2017. Available at www.health.qld.gov.au/__data/assets/pdf_file/0023/634163/med-cannabis-clinical-guide.pdf [Accessed 5 March 2018].
[5] The National Academies of Sciences, Engineering and Medicine. The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research. Washington, DC: NASEM, 2017. Available at www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24625 [Accessed 5 March 2018].