



RACGP

# *The regulatory framework for medicinal use of cannabis products*

Position Statement – March 2018

## Position

The current process of prescribing medicinal cannabis products in Australia is highly bureaucratic, time consuming and expensive, 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 the 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<sup>1</sup> to the *Narcotic Drugs Act 1967*<sup>2</sup> 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.

In response, The Royal Australian College of General Practitioners (RACGP) developed a [position statement](#) in October 2016, which outlined our 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 medical conditions that can warrant prescribing, are not stipulated in legislation, and are reviewed on a case-by-case basis. Approval from both the federal and state/territory governments must be obtained before medicinal cannabis products can be prescribed, which creates a two-tier system.<sup>3</sup>

There is currently no national regulatory framework for prescribing medicinal cannabis products, and it is unclear how (or whether) general practice will be included in this framework. The current regulatory

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complexities and differences between states and territories around accessing medicinal cannabis products are significant barriers for GPs (Table 1).<sup>4</sup>

**Table 1. Prescribing medicinal cannabis products – Jurisdictional differences\***

<b>Jurisdiction</b>	<b>Prescriber</b>	<b>Jurisdiction-specific information</b>	<b>Affected legislation</b>
Australian Capital Territory (ACT)	<ul style="list-style-type: none"> <li>Specialists only</li> <li>General practitioners (GPs) may apply, but require specialist support under the Special Access Scheme (SAS) – Category B</li> </ul>	Clinicians are advised to simultaneously apply to the TGA and ACT Health for faster approval and access	<i>Medicines, Poisons and Therapeutic Goods Act 2008</i> Australian Capital Territory Government laws – General
New South Wales (NSW)	<ul style="list-style-type: none"> <li>Specialists only</li> <li>GPs may apply, but require specialist support under the SAS – Category B</li> </ul>	Clinicians are advised to simultaneously apply to the TGA and NSW Health for faster approval and access	<i>Drug Misuse and Trafficking Act 1985</i> New South Wales Government laws – General
Victoria	<ul style="list-style-type: none"> <li>Specialists</li> <li>GPs may apply, but may require specialist support under the SAS – Category B</li> </ul>	Clinicians are advised to simultaneously apply to the TGA and the Victorian Department of Health and Human Services (Schedule 8 treatment permit) for faster approval and access	<i>Drugs, Poisons and Controlled Substances Act 1981</i> <i>The Therapeutic Goods (Victoria) Act 2010</i> Victorian Government laws – General
Northern Territory (NT)	<ul style="list-style-type: none"> <li>Specialists only</li> <li>GPs can assist specialist with ongoing prescriptions</li> </ul>	Contact NT Chief Health Officer for further information	<i>Misuse of Drugs Act</i> Northern Territory Government laws – General
Queensland	<ul style="list-style-type: none"> <li>Specialists – Can apply to be patient-class and/or single patient prescriber</li> <li>GPs – Can only apply to be a single-patient prescriber</li> </ul>	Complete the Queensland Health Approval Form	<i>Drug Misuse and Act 1986</i> <i>Police Powers and Responsibility Act 2000</i> Queensland Government laws – General
South Australia (SA)	<ul style="list-style-type: none"> <li>Specialists only</li> <li>GPs may apply, but require specialist support</li> </ul>	Clinicians are advised to simultaneously apply to the TGA and SA Health for faster approval and access	<i>Controlled Substances Act 1984</i> <i>Summary Offences Act 1953</i> South Australian Government laws – General
Tasmania	<ul style="list-style-type: none"> <li>Specialists only</li> <li>GPs are not authorised to apply</li> </ul>	Contact Pharmaceutical Services Tasmania for more information. A separate medical cannabis controlled access scheme (CAS) was established	<i>Misuse of Drugs Act 2001</i> Interpretation: <i>Poisons Act 1971</i> Tasmania laws – General
Western Australia (WA)	<ul style="list-style-type: none"> <li>Specialists only</li> <li>GPs may apply, but require specialist support</li> </ul>	Complete the WA Health Approval Form	<i>Cannabis Law Reform Act 2010</i>

\*Information correct at 1 March 2018

## Prescribing medicinal cannabis products

In general, GPs can only gain access to medicinal cannabis products through the Special Access Scheme (SAS), in consultation with, and with the support and approval of a specialist treating the medical condition. GPs generally cannot access the Authorised Prescriber Scheme (APS).<sup>3</sup>

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 valid for three to six months, after which the application process must be repeated for treatment continuity.<sup>3</sup>

## 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,<sup>5,6,7</sup> 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. State and federal governments should consider this.

## 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

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- <sup>1</sup> Commonwealth of Australia. Narcotic Drugs Legislation Amendment Act 2016. Canberra: Commonwealth of Australia, 2016.
  - <sup>2</sup> Commonwealth of Australia. Narcotic Drugs Act 1967. Canberra: Commonwealth of Australia, 1967.
  - <sup>3</sup> Therapeutic Goods Administration. Access to medicinal cannabis products. Canberra: TGA, 2017. Available at [www.tga.gov.au/access-medicinal-cannabis-products](http://www.tga.gov.au/access-medicinal-cannabis-products) [Accessed 12 February 2018].
  - <sup>4</sup> Lambert Initiative for Cannabinoid Therapeutics. State and territory requirements. Sydney: State and Territory requirements, 2017.
  - <sup>5</sup> 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](http://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-overview) [Accessed 5 March 2018].
  - <sup>6</sup> 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](http://www.health.qld.gov.au/__data/assets/pdf_file/0023/634163/med-cannabis-clinical-guide.pdf) [Accessed 5 March 2018].
  - <sup>7</sup> 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](http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24625) [Accessed 5 March 2018].