

# STAKEHOLDER CONSULTATION

## DRAFT NSW CANNABIS MEDICINES PRESCRIBING GUIDANCE

### BACKGROUND

Many Australians are now able to access cannabinoids for medicinal purposes under the supervision of a medical practitioner. Whilst this offers hope to many in the community, medicinal cannabinoids are new in the clinical setting and, with rapidly emerging formulations and products, and diverse routes of delivery, we face a significant scientific evidence gap on how to use cannabis medicines safely. In particular, insufficient information exists to guide medical practitioners in prescribing medicinal cannabis, including appropriate starting and maintenance dosing across a range of medical conditions and drug-drug interactions.

In late 2017, the Therapeutics Goods Administration (TGA) release a suite of guidance documents<sup>1</sup> designed to provide information about the current state of clinical evidence and raise awareness of how to prescribe medicinal cannabis in Australia under current access schemes. These guidance documents provide a synthesis of the best available clinical evidence for the use of cannabis medicines to alleviate symptoms of certain conditions including multiple sclerosis, epilepsy, chronic pain, palliative care and chemotherapy-induced nausea.

In 2018, ACRE received funding through NSW Health's Clinical Cannabis Medicines Program, to develop practical *Prescribing Guidance* to provide interim information to support NSW medical practitioners in prescribing cannabis medicines to patients for conditions where cannabinoids are perceived to have some benefit.

### ABOUT THE DRAFT PRESCRIBING GUIDANCE DOCUMENTS

These draft *Prescribing Guidance* documents are intended to give interim practical information to assist NSW medical practitioners in their decision-making around prescribing and managing the use of cannabis medicines for patient conditions. They draw extensively on the TGA's guidance documents and, as such, require medical practitioners to review the TGA's guidance before making a decision to prescribe cannabis medicine products.

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<sup>1</sup> See <https://www.tga.gov.au/medicinal-cannabis-guidance-documents>

Unlike clinical guidelines, which are underpinned by a strong, available evidence base, these draft *Prescribing Guidance* documents are designed to offer practical suggestions to medical

practitioners around the therapeutic use of cannabis medicines in lieu of the availability of full evidence-base.

Making interim *Prescribing Guidance* accessible for medical practitioners is now critical, given the increasing availability and use of cannabis medicines within NSW for range of medical conditions in advance of evidence-based dosing and knowledge of drug-drug interactions. Where scientific evidence on cannabis medicines is lacking, expert consensus<sup>2</sup> has informed the development of these draft *Prescribing Guidance* documents.

A total of six (6) draft *Prescribing Guidance* documents have been developed to provide guidance to NSW medical practitioners around the use of cannabis medicines in:

- Anorexia Cachexia
- Chemotherapy Induced Nausea and Vomiting (CINV)
- Nausea in Palliative Care
- Dementia
- Non-Cancer Pain
- Spasticity

Recognising that the use of cannabis medicines within the therapeutic setting is changing rapidly, it is expected that the development and review of these *Prescribing Guidance* documents will be an ongoing process. As such, ACRE will review the *Prescribing Guidance* documents annually and update the guidance as new evidence becomes available.

## **WHO DEVELOPED THESE DRAFT PRECRIBING GUIDANCE DOCUMENTS?**

Pharmacologists, pharmacists and clinicians from ACRE, the University of Newcastle Clinical Pharmacology Group and the NSW Cannabis Medicines Advisory Service were involved in the preparation and development of the initial draft *Prescribing Guidance* documents, including:

- Professor Jennifer Martin
- Dr Catherine Lucas
- Associate Professor Jennifer Schneider
- Dr Joanne Patel

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<sup>2</sup> See 'Who was involved in preparing the draft *Prescribing Guidance* documents?'

- Dr Jessica Ryan

Draft *Prescribing Guidance* documents were also provide to the ACRE Clinical Advisory Group, comprised of relevant subject matter specialists<sup>3</sup>, for review and feedback prior to opening the Stakeholder Consultation process.

## ABOUT THE CONSULTATION

The purpose of this consultation is to seek feedback on the suitability of the draft *Prescribing Guidance* documents from a wide range of stakeholders who have an interest in the therapeutic use of cannabis medicines, or anticipate using the guidance to inform their clinical practice. These stakeholders, include but are not limited to:

- Clinicians and medical practitioners
- Health care professional organisations, colleges, societies and associations
- Patient and Consumer Representative groups
- Other medicinal cannabis research groups

ACRE invites stakeholders to provide both general feedback on the suitability of the draft *Prescribing Guidance* documents, and responses to the following questions:

- Are the draft *Prescribing Guidance* documents useful, clear and applicable to current clinical practice?
- Do the *Prescribing Guidance* documents reflect what the evidence says about treatment and care?
- Do the *Prescribing Guidance* documents include all the relevant information?
- Are there gaps in the available evidence and/or therapeutic management options in the *Prescribing Guidance* documents?

Although the *Prescribing Guidance* documents have been specifically developed or NSW-based medical practitioners, ACRE welcomes feedback from stakeholders based across Australia.

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<sup>3</sup> See <https://www.australiancannabinoidresearch.com.au/our-researchers> for ACRE Clinical Advisory Membership

## CONSULTATION TIMELINE

	OPEN	CLOSE
Public Stakeholder Consultation	Wednesday 30 January, 2019	Friday 8 March, 2019
Consolidation of Stakeholder Feedback and revision of draft Prescribing Guidance	Monday 10 March, 2019	Friday 22 March, 2019
Final <i>Prescribing Guidance</i> documents and consultation submissions published on ACRE website	Monday 24 March, 2019	

## CONSULTATION SUBMISSIONS

ACRE invites stakeholders to provide written submissions addressing either a single *Prescribing Guidance* document, a sub-set of, or all of the draft *Prescribing Guidance* documents.

Please email written submissions (in Word format) [ACRE-contact@newcastle.edu.au](mailto:ACRE-contact@newcastle.edu.au) by close of business on **Friday 8 March 2019**.

Submissions will typically be published on the ACRE website, unless specifically requested otherwise. However, ACRE retains the right to not publish submissions that contain offensive or defamatory comments, or do not fall within the scope of the consultation.

When finalised, the *Prescribing Guidance* documents will be published on ACRE's website for public access. The final versions of the *Prescribing Guidance* documents will also be sent to all stakeholders who provided written submissions to the consultation and key NSW-based users. They *Prescribing Guidance* documents are intended to be dynamic documents, reviewed and updated annually and/or as new evidence emerges.

## ABOUT ACRE

The Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE) has been established through the National Health and Medical Research Council (NHMRC) Centre of Research Excellence scheme. It draws together over twenty Australian research leaders and clinicians from major national universities and research institutions to establish a research evidence base to inform safe clinical use of medicinal cannabinoids and to guide policy as cannabinoids are introduced into therapeutic practice in Australia.

## FURTHER INFORMATION

For further information on this consultation process, please email [ACRE-contact@newcastle.edu.au](mailto:ACRE-contact@newcastle.edu.au)

## **FUNDING**

NSW Health through the NSW Clinical Cannabis Medicines Program supported development of these draft prescribing guidance documents.