MULTIPLE SCLEROSIS AUSTRALIA
MULTIPLE SCLEROSIS RESEARCH AUSTRALIA

Submission to the consultation for the Draft Prescribing Guidance of the Australian Centre for Cannabinoid Clinical and Research Excellence

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About Multiple Sclerosis Australia

MS Australia (MSA) is the national peak body for people living with multiple sclerosis (MS) in Australia. Our role is to work on behalf of all state and territory based member organisations to provide a voice for people living with multiple sclerosis across the country to support the development of:

- Research
- Advocacy and Awareness
- Communication and Information
- Services provided by our member organisations
- International Collaboration

MSA advocates across all stakeholders, governments and communities, on behalf of our members, to represent people who are diagnosed with the disease, their carers and the broader MS community.

Our Vision

Is consistent with the vision of the Multiple Sclerosis International Federation – **'A world without MS'**

Our Mission

MSA will support our members and work towards meeting the needs of people with MS, their families and carers. We will facilitate a national comprehensive representation of the Member organisations through advocacy and communication.

Our Purpose

On behalf of our members and people with MS, our purpose is to develop:

- **Research:**
  Supporting ongoing research to pursue further knowledge in targeting prevention, improving treatment, enhancing quality of life and ultimately, to find a cure.
- **Advocacy and Awareness:**
  Although MS impacts people differently, there are common, fundamental issues for people affected by the disease. We are steadfastly committed to giving these people a voice and remain willing and able to work with government and the Australian society to champion issues in a dynamic policy environment to bring about change to the lives of people living with this disease.
- **Communication and Information:**
  Utilising traditional, contemporary and innovative channels to source information and share it with people with MS, our member organisations and our key stakeholders.
- **Support for our member organisations:**
  As MS specialists providing and facilitating high quality services that span the life-time needs of people affected by MS and other degenerative neurological conditions, their families and carers – from the point of early symptoms and pre-diagnosis, that addresses their changing needs.
- **International Collaboration:**
  Representing the MS cause and promoting collaboration with our domestic and international partners.

About Multiple Sclerosis Research Australia

MS Research Australia is the largest not-for-profit organisation dedicated to funding and coordinating MS research in Australia.

Our Mission is to accelerate Australian MS research toward the prevention, better treatments and a cure for MS.

As a member of the MS Australia network, MS Research Australia achieves our mission by working in partnership with relevant medical research institutes and scientists around Australia, encouraging collaborations and focusing on Australian strengths in this research. MS Research Australia is ultimately working towards *freedom from MS*.

Our research strategy aims to accelerate research activity in areas where Australian scientists can have the greatest impact in worldwide MS research. We work in close partnership with and encourage collaboration between a number of Australia's top medical research centres.

MS Research Australia is guided by an informed scientific agenda to accelerate advances and focus on funding research that will increase our understanding of the triggers for MS, the biology driving MS and how we may prevent the ongoing damage caused by MS and repair existing damage that can reverse disability. We also encourage research that will lead to improvements in symptom management, rehabilitation and support services to help people with MS maintain quality of life. We currently fund over 50 investigator-led projects and 7 national collaborative platform projects to advance our understanding of MS.

Together with a robust governance structure, MS Research Australia believes this approach will result in further significant breakthroughs in the knowledge and effective treatment of MS and major steps toward understanding the cause and developing the cure.

Introduction

MS Australia (MSA) and MS Research Australia welcome the opportunity to provide a submission to the consultation for the Draft Prescribing Guidance for Australian Centre for Cannabinoid Clinical and Research Excellence, March 2019**.**

There are currently 25,600 people living with MS across the country and this number is increasing. MS can be a particularly debilitating disease with an unpredictable disease course that affects people in different ways. For some it is a disease with periods of unpredictable relapse and remission. For others it is a progressive decline over time. For all, it is life changing.

As such, MSA and MS Research Australia together support any proven treatment that has been deemed safe by the Therapeutic Goods Administration and that helps to minimise the impact of the disease and allow people with MS to live more fulfilling lives.

A 2004 international survey of over 2,500 people with MS conducted by Australian researchers, indicated that around 10% of people with MS believed that cannabis was a factor that can help improve their MS symptoms.[1]

The most significant cannabis-derived product to have been studied for potential benefits in people with MS to date is the Sativex (nabiximols). Its principal active cannabinoid components are the cannabinoids: tetrahydrocannabinol (THC) and cannabidiol (CBD). Sativex is a mouth spray with proven benefits for muscle spasticity and motor control. Muscle spasticity is a significant problem for many people living with MS, affecting over 80% during the course of the disease and negatively impacting mobility and personal independence. Spasticity can cause pain, sleep disturbance and reduced mobility. These symptoms can significantly limit a person’s quality of life as they have less energy, ability to complete everyday tasks and social activity. It can also lead to an increased reliance on carers and the health system if symptoms progress to a stage where mobility is significantly hampered or hospitalisation is required.

Response to Prescribing Cannabis Medicines For Managing Spasticity

In response to the availability of Sativex for the treatment of spasticity in MS, the Therapeutic Goods Administration developed guidelines for the use of medicinal cannabis to treat MS. The ACRE Guidance document for managing spasticity rightly references these extensive guidelines which cover a range of symptoms that might be part of a person’s MS including spasticity. The document also notes that while the evidence for use in cases of MS spasticity is weak, it is more developed than for other conditions and as such has approval by the TGA.

The remainder of the document is written for conditions other than MS, but we agree with the information provided on best practice management for spasticity including the use of a validated tool to assess spasticity and the other medication and non-pharmacological interventions that might be considered. Note in the flowchart for “Best Practice Guidance for Spasticity” the sentence “Consider the possible impact of treatment – could decreasing spasticity negatively impact function in this patient?” needs to be reworded if the response to this decision is to be “No”.

We also agree with the presentation of information in the “Evidence for Use”, “Adverse Effects”, “Dosing” and “Monitoring Outcomes” sections of this document. The Dosing section in particular is detailed and helpful, in terms of consideration for titrating dose and patient characteristics, what we feel is missing is where in the flowchart of “Best Practice Guidance” the

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[1] Simmons RD, Ponsonby AL, van der Mei IA, Sheridan P, *What affects your MS? Responses to an anonymous, Internet-based epidemiological survey*, Mult Scler. 2004 Apr;10(2):202-11.

use of cannabis medicines might fit, i.e. are they an appropriate second line therapy to be considered once first line systemic medications have failed. Note in the TGA multiple sclerosis guidelines it is recommended that "In the absence of evidence comparing cannabinoids to first line treatments for pain and spasticity in MS, including baclofen, dantrolene, and benzodiazepines, there is no basis for using cannabinoids as a monotherapy or first line treatment. If pain and spasticity are not properly controlled by standard therapies, doctors may discuss with their patients the use of nabiximols or dronabinol as an adjunctive therapy." The ACRE Guidance document may also benefit from a recommendation of where medicinal cannabis falls in the therapeutic hierarchy.

Prescribing Cannabis Medicines For Non-Cancer Pain

People with MS also use medicinal cannabis for the treatment of pain associated with their MS and as such we would also like to comment on the guidelines for use with respect to "non-cancer pain". We agree with the information set out in this document and the guidance of the use of medicinal cannabis as an adjuvant intervention and where it fits within the therapeutic hierarchy for pain (i.e. to not replace currently available first line therapies for pain).

As for the spasticity information above, the TGA provided guidelines on the use of medicinal cannabis for pain for people with MS. Please see https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-treatment-multiple-sclerosis-australia#evidence-pain for more details. As these TGA guidelines are referenced in the ACRE spasticity document, it may be relevant to reference the equivalent information on pain in MS from the TGA in the ACRE document. This reference may fit in the section "Evidence for Use" with a specific note to its use for pain in MS.

Conclusion

Both MS Australia and MS Research Australia are committed to supporting the provision of proven therapies for improving the lives of people with MS. We thank the ACRE for the opportunity to provide a submission to the consultation for the Draft Prescribing Guidance documents on behalf of Australians living with MS.