



**MULTIPLE SCLEROSIS AUSTRALIA
MULTIPLE SCLEROSIS RESEARCH AUSTRALIA**

**Submission to the Therapeutic Goods
Administration Consultation: Proposed
amendments to the Poisons Standard
regarding cannabidiol**

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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 Therapeutic Goods Administration (TGA) Consultation: Proposed amendments to the Poisons Standard regarding cannabidiol (CBD).

The focus of the comments, suggestions and recommendations provided in this submission are specifically on key areas that will impact on people affected by MS.

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.

Overall approach to medicinal cannabis for treating MS symptoms

MSA and MS Research Australia together support any proven treatment that has been deemed safe by the TGA 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), but it is not considered a “low dose” CBD product and is therefore outside the scope of this consultation.

Anecdotes received from members of the MS community indicate that they are receiving benefits from the use of cannabis products to treat MS symptoms such as pain and spasticity.

MS Research Australia has a webpage dedicated to providing the latest research information about medicinal cannabis and details about the effectiveness of medicinal cannabis in treating MS symptoms, its side effects and how to access medicinal cannabis in Australia. Please visit: <https://msra.org.au/medicinal-cannabis-ms/>. The following extracts from the MS Research Australia webpage give a snapshot of the current research evidence regarding medicinal cannabis:

- Research has shown that medicinal cannabis can be useful to treat some of the **symptoms** of MS in some people. There is limited evidence that medicinal cannabis can have an effect on the disease course itself, by reducing the number of relapses, or slowing the progression of the disease and accumulation of disability.
- Human trials using medicinal cannabis to treat **muscle spasticity** have produced positive results overall, where it reduced frequency of spasms and pain associated with spasms, suggesting that medicinal cannabis can be effective for the treatment of spasticity.
- The scientific evidence that medicinal cannabis reduces **pain** in people with MS is varied and there is currently less certainty about its benefits than there is for spasticity in MS.

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.

- In several studies, medicinal cannabis was found to improve a range of **urinary issues**, including the volume and number of urinary incontinence episodes during the day and night and the number of voids per day. Participants also felt that their bladder symptoms improved.
- Improvements in **sleep disturbances** due to a reduction in spasticity or neuropathic pain have been seen in some studies.
- Trials have noted an improvement in **sleep quality** and reduced sleep disturbance in people taking medicinal cannabis, but these changes were only small.

There are risks to consider regarding the availability of medicinal cannabis products. All medicinal products derived from cannabis require strict regulation and standardised doses of active ingredients, to ensure products are safe and effective, and can produce reliable effects with a controlled risk of adverse events.

Robust and reliable evidence is needed to determine the possible benefits and risks of cannabis-based products for managing symptoms of chronic illnesses such as MS. We have previously noted that Sativex, for example, is not a disease modifying treatment, and while this treatment has clinical trial data and approval for spasticity, there may be other MS symptoms that may benefit from cannabis-based products which could be investigated in clinical trials. As part of any debate on this issue, MSA and MS Research Australia encourage the promotion of randomised controlled clinical trials to be conducted to determine the components, dosage and frequency of either cannabis or cannabis-based products and their efficacy and safety for managing a range of symptoms for people living with chronic conditions like MS.

As such, MS Research Australia and MSA also support the TGA framework set out for clinical trial approval to facilitate the treatment of patients enrolled in a recognised medicinal cannabis clinical trial to ensure that medicinal cannabis products can be tested for efficacy and safety within in a safe and supportive medical environment.

The proposed amendments

This submission addresses the two proposed amendments regarding CBD. The first addresses an application to amend the scheduling of CBD, item 2.2, the second addresses the delegate-initiated proposal regarding CBD, item 2.5.

Application to amend the scheduling of cannabidiol, item 2.2

In summary, our understanding is that this proposal is to regulate “low dose” CBD formulations as a complementary medicine in the same way that other plant medicines (herbal medicines) are regulated in Australia.

Both MS Australia and MS Research Australia are committed to supporting the provision of clinically **proven** therapies for improving the lives of people with MS. Our position is guided by a scientific, evidence-based approach and we have advocated for a regulatory framework that enables access to proven standardised formulations that have been clinically shown to be beneficial for specific medical needs (such as spasticity in MS where other medications are not effective or are contraindicated).

Whilst the reasons for the proposal put forward by the Applicant suggests that there is “clear evidence of benefits, good safety profile and low risk”, we believe that there is currently little evidence of efficacy, safety and risk for people with MS. Further, we believe that the regulation

of CBD in this way, as a complementary medicine, will not provide proven standardised formulations for the MS community.

This amendment could substantially improve access and reduce the cost of low dose CBD formulations to the consumer, however we feel that it is still necessary to prove scientifically that the product would safely and effectively treat specific MS symptoms and be of benefit to people living with MS.

MS Australia and MS Research Australia are opposed to this amendment.

Application to amend the scheduling of cannabidiol, item 2.5

In summary, our understanding is that this proposal is to create a new Schedule 3 (Pharmacist Only Medicine) entry for CBD at doses up to 60 mg/day or less.

MSA and MS Research Australia remain concerned that, as stated in the Review on the safety of low dose cannabidiol, there are only limited published studies available regarding the safety, efficacy and risk of CBD and few if any related to use of low dose CBD to treat MS symptoms.

The Schedule 3 proposal does include some safeguards to mitigate safety risks, such as:

- pharmacist advice to mitigate safety risks associated with CBD's high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs
- ability for consumer to identify the symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use
- supply limited to 30 days at which point the consumer and pharmacist can discuss efficacy and continued use
- requirement that both Product Information and Consumer Medicine Information is available to reinforce and/or expand on the safe use of CBD.

MSA and MS Research Australia agree with the proposal that Schedule 3 provides an appropriate level of health professional advice while increasing accessibility of CBD.

MS Australia and MS Research Australia support this amendment.

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.

MS Australia and MS Research Australia understand and acknowledge that people affected by MS will wish to investigate all options available to them to maintain their quality of life, whilst wanting the evidence-based reassurance that medications are safe, effective and affordable.

As stated earlier, our position on these issues is guided by a scientific, evidence-based approach and we advocate for a regulatory framework that will enable access to proven standardised formulations that have been clinically shown to be beneficial for specific medical needs (such as spasticity in MS where other medications are not effective or are contraindicated), while providing regulation that facilitates and encourages further research.