

## Online submission to PBAC regarding nabiximols (Sativex®) for spasticity in MS

### Submissions to be lodged by 12 February at:

[https://www.health.gov.au/internet/main/publishing.nsf/Content/PBAC\\_online\\_submission\\_form](https://www.health.gov.au/internet/main/publishing.nsf/Content/PBAC_online_submission_form)

**Medicine:** nabiximols (Sativex®)  
**Submitted by:** MS Australia  
**Email:** [andrew.giles@msaustralia.org.au](mailto:andrew.giles@msaustralia.org.au)  
**Phone:** 0417 393 842  
**Address:** Level 19, 100 Miller St, North Sydney, NSW 2060

### Declaration of interest:

MS Australia is making this submission as we have an interest in the health and well-being of all people with Multiple Sclerosis (MS). MS Australia is the national peak body for people living with MS in Australia. We work with governments at all levels, engaging on the issues that concern the lives of people living with MS, their families and carers, the community and the economy. We declare that we have in the past received funding support from pharmaceutical companies with an interest in MS in the form of grants for projects, though not from Emerge Health Pty Ltd.

### Consumer input:

MS Australia is writing to support the inclusion of the medication nabiximols (brand name Sativex®) to the Pharmaceutical Benefits Scheme (PBS) for the treatment of patients with spasticity due to MS. As the national peak body for people with MS we are proud to advocate on behalf of our member organisations and the MS community. One area we are particularly passionate about is the provision of more affordable and accessible treatments that can improve the lives of people with MS.

There are currently more than 25,600 people living with MS across the country and over 7.6 million Australians know or have a loved one with this potentially debilitating disease. MS can be particularly debilitating and has an unpredictable disease course. No two cases of MS are the same. There is no one-size fits all treatment for people living with MS and to date, there is no known cure.

In recent years, MS Research Australia and MSA have made numerous submissions to various government enquiries regarding the regulation of medicinal cannabis in Australia, including the most recent Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia.

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 further research.

As the national peak body for the Australian MS community, we also understand the frustration currently being experienced by many people in the MS community in Australia, their families, carers and friends, who, anecdotally, feel they are receiving great benefit from the use of cannabis and are seeking changes to the regulatory framework to make medicinal cannabis products more easily accessible, affordable and better understood.

Sativex (a mouth spray based on the cannabis derived ingredient nabiximols containing both THC and CBD compounds) was the first medicinal cannabis product approved in Australia by the Therapeutic Goods Administration (TGA) in 2012 for the treatment of muscle spasticity in people with MS. Sativex was approved because the clinical trial results showed patients receiving Sativex had a greater reduction in their symptoms of spasticity related to MS and associated symptoms including pain and sleep disturbances, compared to standard treatment alone.

Muscle spasticity is a significant problem for many people living with MS, affecting up to 90% 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.

It was not possible to access Sativex in Australia until there were changes to the regulations. Since 6 November 2017, Sativex became accessible through specific access schemes depending on the state or territory. It can be prescribed for the treatment of moderate to severe muscle spasticity in people with MS who have not responded adequately to other anti-spasticity medications, yet for many people with MS it remains unaffordable.

Here are just three examples of the many comments we received from people with MS regarding the submission to list Sativex on the PBS:

- *The cost of it is just unobtainable for the average working person let alone on a disability pension. I did manage to obtain a couple of bottles because I didn't have to pay for it. It stopped 90% of my muscle spasms and let me think that life could be bearable again only to run out and not be able to get hold of any more either because I couldn't get a script or afford to buy it.*
- *It's too expensive, I have try some taken just at night and it's amazing I can get out of bed in the morning, sleep better don't feel fatigue thought the day no pain, my mood different. I just wish it was a lot cheaper.*
- *This made a huge difference to my husband's PPMS. He was lucky to be on a trial thanks to his amazing neurologist. Without it being funded, there is no way we could have been able to afford it. It is devastating to know that there is medication but that it is no accessible due to the cost. Medical treatment options should not be decided based on cost.*

There is a great deal of interest in the listing of Sativex on the PBS from the MS community and MS Australia receives many comments on our social media channels when we post about this issue. These comments include comparisons with other treatments for spasticity that have been prescribed for people with MS but which cause unpleasant side effects.

Including this medication on the PBS will make a valuable addition to the repertoire of medications available to people with MS, and their doctors. It will allow for an expanded treatment choice to be made according to the efficacy and possible side-effects in relation to an individual's circumstances and will help to alleviate the economic cost of MS to individuals, their families and the broader community.

Our colleagues at MS Research Australia will be making a submission that includes detailed research information regarding nabiximols (Sativex®).

We appreciate you considering this treatment for inclusion on the PBS.

**How did you learn about this consumer submission process?**

From PBAC web-site.

**SUBMIT (BUTTON)**