Multiple Sclerosis Research Australia
1300 356 467 • info@msra.org.au • www.msra.org.au
Level 19, Northpoint 100 Miller Street • North Sydney • NSW 2060
PO Box 625 • North Sydney • NSW 2059
ABN 34 008 581 431

MS Research Australia is writing to support the inclusion of Sativex (nabiximols) on the Pharmaceutical Benefits Scheme (PBS) for people with MS experiencing symptoms of moderate to severe muscle spasticity.

As the largest national not-for-profit organisation dedicated to funding MS discoveries and coordinating MS research in Australia, we are proud to advocate on behalf of people affected by this disease. The affordable availability of evidence-based treatments for MS is the greatest un-met need facing the MS community worldwide.

Muscle spasticity is a significant problem for many people living with MS, causing pain, disturbed sleep and reduced mobility. In turn, this has a large impact on the quality of life and inclusion in employment and social activities. Unfortunately, therapeutic options for muscle spasticity are currently limited. The medicinal cannabis-based mouth spray, Sativex, has been registered for use for people with MS with moderate to severe muscle spasticity by the Therapeutic Goods Administration (TGA). By being included on the PBS, this treatment would provide a choice for patients with spasticity for whom current medications are contraindicated or ineffective.

One in twenty Australians will be affected by MS throughout their lifetime; whether directly, or through a family member, work colleague or friend. MS is most commonly diagnosed when an individual is of working age and can have an impact on job productivity. MS costs the Australian community over $1.75 billion per year[1] and nearly 50% of this cost is due to lost productivity of people with MS and their carers. Spasticity can increase the reliance of people with MS on their carers. Sativex represents a new choice of symptom modifying therapy for people with MS who experience spasticity.

MS Research Australia believes the subsidy of this treatment may help many people with MS remain active in their communities and in the workforce for longer periods of time, therefore decreasing the cost of lost productivity on the national economy and increasing the quality of life for people with MS. Affordable access to new treatments that can better manage the disease are of crucial importance to people with MS and to the Australian community. MS Research Australia welcomes new treatments that have undergone rigorous clinical testing as a way of giving people living with MS more options in reducing the impact of the disease on their lives.

Two clinical trials, divided into a 4-week treatment phase to identify initial responders followed by a 12-week randomised, placebo-controlled phase, have shown Sativex to be an effective treatment to significantly reduce moderate to severe muscle spasticity in people with MS[2,3]. Both trials investigated Sativex as an add-on therapy to standard anti-spasticity treatment.

In the first phase 3 trial[2], 572 people with MS took part in the initial phase, with 272 people achieving ≥20% improvement in muscle spasticity. Following this, 241 initial responders progressed to the randomised, placebo-controlled phase. The mean spasticity score improved a further 0.04 points for

those treated with Sativex, whereas those treated with placebo exhibited a mean deterioration of 0.81 points (overall difference between groups of 0.84 points; p = 0.0002). Furthermore, a significantly higher proportion of participants exhibited ≥30% improvement in spasticity in the treatment group (74%) compared to the placebo group (51%) (p = 0.0003). Sativex was also significantly superior to placebo for spasm frequency (p = 0.005) and sleep disruption (p < 0.0001).

In the SAVANT trial[3], 134 of the 191 people who took part in the initial phase had ≥20% improvement in muscle spasticity. Of the 106 people who were randomised into the second placebo-controlled phase, 77.4% of people treated with Sativex exhibited ≥30% improvement in spasticity compared to 32.1% in the placebo group (p < 0.0001). In addition, both mean MS spasticity (P < 0.0001) and spasm severity (p = 0.0001) were significantly reduced in the Sativex group compared to the placebo group.

Sativex has been shown to be well-tolerated by people with MS. In the phase 3 trial, the adverse event rate was similar between Sativex and placebo, with the most common adverse events in the treatment group being vertigo, fatigue, dizziness and somnolence[2]. The results were similar in the SAVANT trial, with the most common adverse events being vertigo, somnolence, dizziness, diarrhoea and nausea[3].

MS Research Australia supports affordable access to all proven treatment options to increase the opportunity for people with MS and their doctors to find effective therapies suited to their individual circumstances. Reducing muscle spasticity will improve the quality for people with MS and their loved ones, enabling participation in social and family life, and employment.

MS Research Australia appreciates the opportunity to make this submission and applauds the Committee for seeking the views of people with MS and the wider community as part of the process of considering new MS treatments for inclusion on the PBS.


1) Health Economic Impact of MS in Australia in 2017. https://msra.org.au/wp-content/uploads/2018/08/health-economic-impact-of-ms-in-australia-in-2017_ms-research-australia_web.pdf
2) A randomized, double-blind, placebo-controlled, parallel-group, enriched-design study of nabiximols* (Sativex(®)), as add-on therapy, in subjects with refractory spasticity caused by multiple sclerosis. Novotna A, Mares J, Ratcliffe S, Novakova I, Vachova M, Zapletalova O, Gasperini C, Pozzilli C, Cefaro L, Comi G, Rossi P, Ambler Z, Stelmasiak Z, Erdmann A, Montalban X, Klimek A, Davies P; Sativex Spasticity Study Group. Eur J Neurol. 2011 Sep; 18(9):122-31 doi: 10.1111/j.1468-1331.2010.03328.x
3) Sativex® as add-on therapy vs. further optimized first-line ANTispastics (SAVANT) in resistant multiple sclerosis spasticity: a double-blind, placebo-controlled randomised clinical trial. Markovà J, Essner U, Akmaz B, Marinelli M, Trompke C, Lentschat A, Vila C. Int J Neurosci. 2019 Feb; 129(2):119-128 doi: 10.1080/00207454.2018.1481066