MULTIPLE SCLEROSIS AUSTRALIA

Submission to the Department of Health's Review of the National Medicines Policy

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Introduction

MS Australia is pleased to provide a submission to the Department of Health's Review of the National Medicines Policy.

MS Australia is the national voice for people with multiple sclerosis (MS). It is the largest national not-for-profit organisation dedicated to funding MS discoveries and coordinating MS research in Australia; it also works in advocacy and communications, collaborating with stakeholders to benefit thousands of people affected by MS across the country.

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

Accessible and affordable treatments for MS

MS Australia's main interest in the National Medicines Policy is to ensure it provides a framework for timely access to affordable medicines for the MS community.

As the national peak body for people with MS we are proud to advocate on behalf of our state 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 and most intensely so for those with the primary progressive form of MS who, to date, have no treatments available.

There are approximately 25,600 people living with MS across the country and for those living with the relapsing/remitting form of MS (around 85%), there are currently 15 disease-modifying therapies available on the PBS[1]. This number and range of treatments is essential to ensure that people living with MS, who each experience MS differently, and their healthcare teams, have choice in the medicines available to suit each individual's needs and unique circumstances. There is also a range of other medications for the treatment of MS (such as ocrelizumab for the treatment of the primary progressive form of MS) and treatments for MS symptoms (such as fampridine to improve walking and nabiximols to improve spasticity) that are available to people living with MS but are not listed on the PBS, making them much less accessible and affordable.

The challenges faced by people with MS can be significant and can have a devastating impact on their families and the wider community. The progressive forms of MS (around 10-15% of the MS community) inevitably lead to long term disability, resulting in the need for physical and/or psychological care and support, medical investigations, treatments and hospitalisation.

Economic impact of MS

The symptoms associated with MS and the gradual progression of the disease, mean that many people with MS are unable to retain their employment. In fact, people with MS are generally more likely to be unemployed than those with any other chronic disease. This

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[1] https://www.msaustralia.org.au/about-ms/medications-and-treatments

contributes to an increasing economic burden of MS on the rest of society. The economic cost of MS to the Australian community has been estimated to be around $1.75 billion a year.

The economic costs of MS significantly increase as disability increases. As reported in the *Health Economic Impact of MS in Australia in 2017* [2], the costs of MS increase with increasing disability. The costs more than tripled in people with severe disability ($114,813) compared to those with no disability ($30,561). This is also reflected in the value of NDIS plans for people with MS, which average around $60,000 per year, with the value of plans rising to well over $150,000 per year as disability increases.

Therefore, a treatment that can delay the progression of disability can have a significant economic benefit.

Vision for the National Medicines Policy (NMP)

MS Australia agrees with the overarching sentiments contained in the discussion paper that given the rapid advances and developments in all areas of the healthcare landscape in recent years, a review of the NMP is timely.

MS Australia is keen to ensure that the NMP reflects Australia's commitment to medical research and development, and clinical trials that enhances Australia's attractiveness to industry and the broader research community. This includes fostering an environment that encourages confidence amongst industry, strengthens their commitment to bring timely access to new therapeutics, and ultimately, improves patient health outcomes.

MS Australia is a member of the Australian Patient Advocacy Alliance (APAA) and our vision is aligned to that of the APAA, namely:

> *"Our Vision -*
> *A National Medicines Policy that supports all Australians to receive the therapeutics they need at the right time to deliver better health outcomes. A system that enhances consumer participation, is flexible and adapts to advances in technology, and is transparent with established measures to evaluate the success of how it is delivered. "*
> (APAA draft submission to review of NMP, Sept 2021)

Summary of recommendations

Recommendation 1:

MS Australia recommends that a commitment to developing and implementing mechanisms for measuring and reporting against achievement of the principles and objectives be included in the NMP.

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[2] https://msra.org.au/wp-content/uploads/2018/08/health-economic-impact-of-ms-in-australia-in-2017_ms-research-australia_web.pdf

Recommendation 2:

MS Australia recommends that mechanisms be explored under the NMP to bring together key stakeholders such as people affected by MS, MS researchers, clinicians, industry representatives and Department of Health representatives to collectively consider the changing MS landscape and the role of each stakeholder group in maximising health outcomes for the MS community.

Recommendation 3:

MS Australia recommends improving accessibility of TGA and PBAC processes for consumers so their needs and expectations can be heard, and ensuring HCPs are up-to-date with the TGA regulatory regime to reduce barriers for consumers to access proven medicines. Further, MS Australia recommends that health policy information and processes be made available in plain English to improve understanding and assist with the involvement of the broadest and most diverse range of consumers possible.

Terms of reference

This submission is set out in accordance with the terms of reference provided in the NMP discussion paper.

1. **Evaluate the current NMP objectives and determine whether these should be modified, or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.**

MS Australia believes that the current objectives and principles of the NMP are suitable; they are fundamental and laudable. In addition, it would be beneficial to have an NMP that can adapt to the changing health landscape (e.g. COVID-19 pandemic).

We do, however, remain concerned as to how stakeholders know if these objectives and principles are being achieved? Is there a proposed mechanism for measuring and testing progress against achieving these principles and objectives? How and how often will they be reported against? One way would be to track consumer experiences and reported outcomes from medicine use. If there is a breach of these objectives and principles, will this be rectified, and will there be consequences?

Recommendation 1:

MS Australia recommends that a commitment to developing and implementing mechanisms for measuring and reporting against achievement of the principles and objectives be included in the NMP.

2. **Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.**

No comments against this term of reference as it is not considered relevant to the treatment of MS.

3. Assess the NMP’s utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

The MS landscape is rapidly evolving, for example: new effective treatments are being brought to market that delay the progress of disability for many people, generic treatments are being made available, advances are being made in understanding the forms of MS, improved technologies are being introduced to monitor and record changes in the disease course. There is also growing interest and research into effective stem cell transplant treatments.

A recent article in the *American Journal of Medicine*, states that “remarkable advances in treatment of all forms of MS, and especially for relapsing disease, have favorably changed the long-term outlook for many patients. There also has been a conceptual shift in understanding the immune pathology of MS, away from a purely T-cell-mediated model to recognition that B cells have a key role in pathogenesis.

The emergence of higher-efficacy drugs requiring less frequent administration have made these preferred options in terms of tolerability and adherence. Many experts now recommend use of these as first-line treatment for many patients with early disease, before permanent disability is evident.”[3]

Consideration of the long-term impacts of DMTs is also important. A recent study by the Menzies Institute of Medical Research, titled, *The effect of national disease-modifying therapy subsidy policy on long-term disability outcomes in people with multiple sclerosis*, concluded:

“In this study, we have shown that more permissive national-level DMT funding policy is associated with markedly greater DMT use and lower disability, slower rate of disability accrual and higher HRQoL [quality of life] in people with ROMS [relapsing-onset MS]. Furthermore, it suggests that greater DMT utilisation may mediate the association of country with disability outcomes 10–20 years post-diagnosis. These results are important for understanding the effects of DMT funding policy and the long-term outcomes of DMT treatment, as these outcomes are not assessed by clinical trials and are only partially assessed by long-term extensions of such trials.”[4]

There are few, if any, opportunities to discuss or appraise the Department of Health or representatives of the pharmaceutical industry collectively of these developments nor to explore ways to embrace these advancements in treatments for MS to deliver high-quality outcomes for the MS community.

Also, it is currently very difficult for peak consumer/advocacy bodies to interact with the various aspects of the health policy landscape except on a piecemeal basis e.g. by responding to calls for submissions to meetings of PBAC for particular treatments and to inquiries and consultations by the TGA, Parliamentary Committees, or the Department of Health on particular aspects of health policy and regulation.

A person living with MS and their healthcare team do need to be able to consider these advances holistically, to be able to make treatment decisions that are timely and effective and lead to better outcomes for their own individual MS journey.

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[3] Stephen L. Hauser, Bruce A.C. Cree, Treatment of Multiple Sclerosis: A Review, The American Journal of Medicine, Volume 133, Issue 12, 2020, Pages 1380-1390.e2, ISSN 0002-9343, https://doi.org/10.1016/j.amjmed.2020.05.049.

[4] Claflin SB, Campbell JA, Mason DF, et al. The effect of national disease-modifying therapy subsidy policy on long-term disability outcomes in people with multiple sclerosis. Multiple Sclerosis Journal. August 2021. doi:10.1177/13524585211035948

Pharmaceutical companies individually provide a range of patient support programs, produce applications and run various "patient-focused" campaigns. Whilst these endeavours are each designed to assist a person with MS to manage their condition, the number and range can be confusing.[5]

Therefore, the NMP needs to be broad enough in its scope and more encouraging in its approach, to allow for more information sharing and discussions to take between consumer/advocacy bodies, pharmaceutical companies and the Department of Health, for example, to facilitate discussions about research and development, treatments "in the pipeline" and so on.

Consideration could be given, for example, to holding a disease-specific "summit" or "stakeholder forum" to bring together key stakeholders to share information and lead to a better understanding of the MS landscape; what is emerging or "in the pipeline" for say, the next five years. Key stakeholders could include: people affected by MS, MS researchers, clinicians, industry representatives and the Department of Health. The "summit" could lead to a better understanding of the needs and responsibilities of each group of stakeholders, with a particular focus on the needs of people affected by MS and their healthcare teams, and recommendations could be considered on how best to work with the Department of Health to achieve the NMP objectives.

Recommendation 2:

MS Australia recommends that mechanisms be explored under the NMP to bring together key stakeholders such as people affected by MS, MS researchers, clinicians, industry representatives and Department of Health representatives to collectively consider the changing MS landscape and the role of each stakeholder group in maximising health outcomes for the MS community.

4. Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers, and their needs and expectations.

Consumer and carer involvement with the NMP is a core, fundamental principle.

Currently, consumer and carer involvement in TGA and PBAC processes from the MS community is minimal, largely due to the piecemeal approach outlined under term of reference 3 (above) and the difficulty many people affected by MS have in accessing and understanding this information. These approaches need to be made more accessible to the MS community (and the community in general) so their needs and expectations can be heard.

TGA and PBAC processes are complex and often technical, such as the process for listing a new medicine on PBS. Also, an often-reported mistrust of large pharmaceutical companies persists, and it is difficult for a person affected by MS to "imagine" the impact of a new medicine on their life, unless they have participated in the clinical trial. These factors combined lead to a lack of consumer participation, despite the best efforts of peak bodies and advocacy groups.

It is worth noting that not all consumer groups have peak bodies or representatives, e.g. the neuromyelitis optica spectrum disorder (NMOSD) community. So without any support they are excluded from these processes.

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[5] Salimzadeh Z, Damanabi S, Kalankesh LR, Ferdousi R. Mobile Applications for Multiple Sclerosis: a Focus on Self-Management. *Acta Inform Med*. 2019;27(1):12-18. doi:10.5455/aim.2019.27.12-18

Health literacy remains patchy throughout the MS community and many people affected by MS are largely reliant on advice from their neurologist and GP. These HCPs are not always MS specialists and therefore are not up-to-date with the latest MS treatments, leading to poorer health outcomes, delays in effective treatment and progress of disability.

A good example is the many HCPs that are lacking education in the current TGA regulatory regime for prescribing certain medicines to their patients (e.g. medicinal cannabis product Sativex, which is approved by the TGA)[6]. Despite the significant interest in Sativex from the MS community, which has been proven to be effective, many HCPs are reluctant to prescribe it due to the taboo associated with medicinal cannabis and limited knowledge in how to prescribe it through special access schemes, which vary between states and territories. It is necessary to have HCPs up-to-date with the TGA regulatory regime (e.g. through training), including the special access schemes to prescribe these medicines. In fact, introducing a single special access scheme that could be implemented nationwide that HCPs are aware of would improve timeliness in proven treatments and therefore improve health outcomes.

These are barriers that commonly result in consumers attending private clinics and paying hundreds of dollars just for a consultation and prescription from a practitioner who has no prior knowledge of the consumer. This could also lead to consumers purchasing unapproved medicines that may be unsafe, leading to poorer health outcomes. Every person with MS experiences different symptoms so it is necessary for HCPs to be aware of this and to be up to date with the different medicines available to combat these symptoms.

For the reasons outlined above, consumer representation in health policy-related organisations and bodies risks becoming a “profession”, making it difficult for the “ordinary” consumer to understand how to become involved or to find out the latest information.

Many peak consumer bodies are making information available in other languages to assist consumers from culturally and linguistically diverse (CALD) communities to contribute, and providing NMP information in a range of languages other than English is worthy of consideration.

Recommendation 3:

MS Australia recommends improving accessibility of TGA and PBAC processes for consumers so their needs and expectations can be heard, and ensuring HCPs are up-to-date with the TGA regulatory regime to reduce barriers for consumers to access proven medicines. Further, MS Australia recommends that health policy information and processes be made available in plain English to improve understanding and assist with the involvement of the broadest and most diverse range of consumers possible.

5. Identify options to improve the NMP’s governance, communications, implementation (including enablers) and evaluation.

As described above, clear communications, especially in simple English, will benefit all consumers and their carers, and improve understanding and engagement. Mechanisms

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[6] https://www.tga.gov.au/medicinal-cannabis

for determining the quality of these communications must be explored, listened to, implemented and evaluated.

For example, the Medicine Status website[7] was developed in an attempt to improve information for consumers and carers about the process for listing a medicine on the PBS, but it needs further work to make it more easily understandable to the average consumer such as an explanation of the often-long delay between having a medicine recommended by PBAC and then approved for listing on the PBS by the Health Minister.

6. **Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.**

MS Australia works successfully in partnership with many other organisations, so applauds the partnership approach taken through the NMP.

We believe that the NMP partners have been accurately described in the draft NMP documentation and in Recommendation 2 above, we have suggested that mechanisms for these partners to come together collectively are needed to achieve the NMP policy objectives, rather than maintaining a piecemeal approach.

There is a need to build trust though transparency as well as accountability with the broader community. An example is the large number of redactions that are inevitably made to PBAC Public Summary Documents following a PBAC outcome for a particular medicine. Whilst there may be good reasons for the redactions, these are not explained, and this lack of transparency may invite suspicion about what is being hidden from public view in a Public Summary Document.

Conclusion

MS Australia is pleased to have had the opportunity provide a submission to the Department of Health’s Review of the National Medicines Policy and looks forward to further consultation as the new NMP is developed and implemented.

KEY FACTS ABOUT MS:

- Multiple sclerosis (MS) is a neurological condition affecting the central nervous system (brain and spinal cord) that affects more than 25,600 people throughout Australia
- It is the most common chronic neurological condition diagnosed in young adults.
- MS is most commonly diagnosed between the ages of 20 and 40
- 75% of people diagnosed are women.
- MS varies significantly from person to person. For some people, it is a disease that comes and goes in severity with periods of unpredictable relapse and remission. For others it means a progressive decline over time. For all, it is life changing.
- Symptoms vary between people and can come and go; they can include severe pain, walking difficulties, debilitating fatigue, partial blindness and thinking and memory problems.

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[7] https://www.pbs.gov.au/medicinestatus/home.html)