28 January 2022

Hon Michael Sukkar MP
Assistant Treasurer
Minister for Housing, Homelessness, Social and Community Housing
Member for Deakin

Via email: prebudgetsubs@treasury.gov.au
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Dear Assistant Treasurer

2022/23 Pre-Budget Submission

We thank the Minister for Housing and Assistant Treasurer for calling for submissions from individuals, businesses, and community groups about their views regarding priorities for the 2022/23 Federal Budget. We also acknowledge and thank the leadership of the Government's economic team for steering Australia during the pandemic.

The Budget comes at an important time as the nation hopefully enters the tail end of the pandemic leading to an economic recovery. Biogen believes in a shared responsibility to ensure a sustainable healthcare system for all Australians to access the medicines and technologies they require to live healthy and fulfilling lives – which requires a strong and prosperous economy to fund.

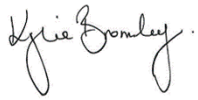
For this to be possible, Biogen's submission focuses on three recommendations: delivery of a national dementia strategy; planning and implementation of a 'Hospital in the Home' model for treatment infusions; and increased investment in genetic diagnosis capabilities and disease registries.

Spinal Muscular Atrophy (SMA) is an example of how cutting-edge medicine has driven advances in technology-driven health care, transforming the 'era of the diagnosis' to the 'era of the cure'. SMA was previously a terminal disease and the leading genetic cause of death for Australian babies under the age of two. Since the Biogen's introduction of the world's first ever SMA medicine called SPINRAZA® (nusinersen) in Australia in June 2018, this is no longer the case. SPINRAZA was announced for funding on the Pharmaceutical Benefits Scheme in the 2018/19 Budget by then Treasurer, the Hon Scott Morrison MP.

Through Biogen's significant innovative medicines portfolio, including life-saving therapies such as SPINRAZA, we are committed to delivering equitable access for all Australians, including vulnerable populations or those in remote and rural Australia. We see our role as active participants and partners in finding the solutions to the healthcare challenges we face as a society. As such, we have made a pre-budget submission providing insights from the coalface of medical research and development in the hope of creating better health outcomes for all Australians.

It is hoped this Budget will deliver tangible policies that allows Australia to remain at the forefront of cutting-edge medicines and technologies to ensure the best health outcomes for
all Australians.

Yours sincerely



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2022/23 Pre-Budget Submission

Australian Treasury

Submission by Biogen

January 2022

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About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercialises biosimilars of advanced biologics, and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology, and neuropathic pain.

For more information, please visit www.biogen.com.au

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Recommendations

Biogen makes the following recommendations to be considered for inclusion in the 2022/23 Federal Budget which would aid in improving the health, economic and social outcomes for the Australian community.

Recommendation 1 – Delivery of a National Dementia Strategy

In 2022, there are an estimated 487,500 Australians living with dementia. The importance of a National Dementia Strategy cannot be underestimated given that without a major medical breakthrough, the number of people with dementia is expected to increase to almost 1.1 million by 2058.[i]

It is understood that the Department of the Health will enter stakeholder consultations in mid-2022 on the development of a new National Dementia Strategy. It is vital that a new National Dementia Strategy be developed, with adequate funding assigned to deliver what will be the strategy's final recommendations. Any further delay in delivering this strategy will be a disservice to those Australians impacted directly and indirectly by dementia now and in the future.

The National Dementia Strategy should incorporate the six key pillars listed in *The Future of Alzheimer's Disease* White Paper that was published in November 2021. The White Paper is a culmination of work where Biogen facilitated the Future of Alzheimer's Disease Think Tank, an event which hosted almost 40 experts from across the Australian health system – including government, primary and speciality care practitioners, nursing, patient advocacy, professional and allied health associations – to discuss and prioritise the system-wide challenges facing the potential introduction of a disease modifying treatment (DMT) for Alzheimer's disease (AD).

Following the Think Tank and an extensive period of consultation amongst key stakeholders, the White Paper recommended the following potential solutions:

i. Improvements in case finding to support early diagnosis
ii. Clarity and structure on diagnostic pathways
iii. Establishing infrastructure and skills to help deliver treatment options
iv. Growing awareness and understanding of the importance of brain health
v. Determining the role of primary care
vi. Establishing system-wide collaboration and integration.

An example of a policy outcome that is aligned with the six recommendations of the White Paper is early diagnosis. The Commonwealth Government should fund regular brain health check-ups for over 45s with their General Practitioner (GP), including completion and tracking of appropriate/up-to-date cognitive function questionnaires. This would benefit all patients with dementia and other diseases affecting the brain. This initiate is similar to the National Bowel Cancer Screening Program, a federally initiative for Australians aged 50-74, that sends people a free bowel screening test in the mail every two years. The streamlined and broad-based proactive program then

sends the results to a patient's GP; My Health Record; and the National Cancer Screening Register to ensure there is early intervention and accurate data collection.[ii]

Additionally, a potential DMT for AD – aducanumab – is currently before the Therapeutic Goods Administration and many other innovators are also researching medicines for dementia. It would be logical that the national dementia strategy includes the potential impacts of a DMT, because when one is approved, it will alter the landscape as to how dementia is treated and also have a major impact on the aged care sector where 54% of people living in permanent residential aged care have dementia.[iii]

The University of Canberra's National Centre for Social and Economic Modelling (NATSEM) report researched the social and economic costs of AD in Australia over a 20-year period, the report is titled *The Economic and Societal Cost of Alzheimer's Disease in Australia, 2021-2041.*[1] The NATSEM report found that if a DMT for AD was available, that by 2041, there would be 4,602 fewer persons with AD in residential aged care;[2] reduce the cost of formal aged care by $7.9 billion and informal care by $4.7 billion; and prevent 7,494 deaths over the 20 years.[iv]

Budget Ask

The Federal Government restates its commitment to the funding and development of a new National Dementia Strategy and its recommendations, which includes appropriate timelines for the development of the strategy and incorporates the potential impact of a DMT on the dementia community.

Recommendation 2 – Planning and implementation of a 'Hospital in the Home' model for treatment infusions

The pandemic has shown the importance of innovative solutions for delivering health care that better suits the needs of patients. Currently, a significant portion of hospital in the home (HITH) services are funded or delivered through private insurers, commercial providers, or state-run hospitals. Further exploration should be conducted to see how the Commonwealth could promote the uptake of HITH to deliver treatments requiring "infusions out of the hospital", such that an increasing number of infusions could be delivered in a home, office, GP clinic, pharmacy, or pathology centre. This would potentially enhance patient access, allow immunocompromised patients to avoid a hospital setting, improve health outcomes, and improve economic productivity by allowing people to spend more time working rather than travelling to a distant hospital.

An efficient manner to deliver treatment infusions that increases patient access and convenience while ensuring adequate medical supervision is through GP clinics. This

[1] The Economic and Societal Cost of Alzheimer's Disease in Australia, 2021-2041 report is in the final stages of drafting and will be released on 9 February 2022. It has been shared in draft form in Appendix 2
[2] As of 30 June 2020, 183,989 people were using permanent residential aged care.

Australian Institute of Health and Welfare, 'People using aged care', 27 April 2021, accessed 13 January 2022, <https://www.gen-agedcaredata.gov.au/Topics/People-using-aged-care>

is especially useful in addressing the needs regional Australia and for patients with mobility issues.

Under the current system, there is no Medicare Benefits Schedule (MBS) item number that allows GPs to claim for a Section 85 medicine that takes between 60 to 120 minutes to infuse, however there is one for Section 100 biologics (MBS 14245). It is recommended that MBS 14245 is expanded to include Section 85 medicines, or a new MBS item number is created to allow GPs to be adequately compensated for the administration of Section 85 medicines that take between 60 to 120 minutes to administer, including parental administration (i.e. intravenous and subcutaneous). Alternatively, MBS 13950 could be broadened to treatments other than antineoplastic treatments, recognising that adequate resources for administration of treatments is required for all disease areas.

The rationale for a focus on short duration treatment infusions is that often the travel time can exceed the infusion time, which can be onerous on patients and their families. Furthermore, the short nature of the infusions, means that if the infusion locations can be decentralised, patients and their families will be able to return to work and not be required to take a whole day off for a medical appointment. In a pandemic climate, where there are worker shortages, it is important to ensure that healthcare delivery is aligned with economic priorities.

Budget Ask

That access to HITH be expanded by amending the MBS to include Section 85 medicines by adding to current MBS item number 14245 or 13950 or creating a new MBS item number allowing for GPs to be adequately compensated for the administration of parenteral (IV and SC) medications that take between 60 to 120 minutes to administer.

Recommendation 3 – Increased investment in genetic diagnosis capabilities and disease registries

Genetic testing for adults

The Genomics Health Futures Mission (GHFM) is an important program that invests $500 million over 10 years in genomic research from 2018/19 to 2027/28. The GHFM improves testing and diagnosis for many diseases, helps personalise treatment options to better target and improve health outcomes, and reduces unnecessary interventions and health costs.[v] The Government should continue its transformative initiative and ensure that funding is made permanent after the initial funding lapses. This is absolutely critical to help tackle conditions such as Amyotrophic Lateral Sclerosis (ALS), enabling those affected to potentially take part in clinical trials and to give them the best chance of accessing treatment if and when it becomes available.

Genetic testing for babies

Eighty percent of rare diseases are genetic, and a disease is considered rare if it affects less than five in 10,000 people.[vi] However there are more than 7,000 rare diseases that are life threatening or chronically debilitating, and around 8% of Australians (two million people) live with a rare disease.[vii]

There are primarily two strategies for genetic testing: (a) preconception genetic testing to prevent the birth of a child with a genetic disease while utilising in vitro fertilization (IVF) to assist with the conception of a healthy child; or (b) after birth genetic testing via newborn screening (NBS) to detect a disease as early as possible to maximise a baby's chance of survival with rapid treatment before symptoms develop and disease progression.

Preconception genetic testing

Both methods are vital, and the Government should be congratulated for the work led by Minister Hunt with Mackenzie's Mission – to screen up to 10,000 couples across Australia for approximately 750 severe, childhood-onset genetic conditions, allowing prospective parents to gain information about their likelihood of having a child with any of these genetic conditions.

The three-year Mackenzie's Mission research study announced in the May 2018 Federal Budget will hopefully lead to the provision of free reproductive genetic carrier screening available to all couples in Australia who wish to have it.

Newborn screening

Diagnosis of a rare disease can often take time because these conditions are complex, and doctors do not see them often. Given many of these diseases are progressive, a delay in diagnosis can mean the difference between life and death or being able to walk or being wheelchair bound.

Until recently, a rare disease known as Spinal Muscular Atrophy (SMA) was the leading genetic cause of death for Australian babies under the age of two. Since Biogen's introduction of the world's first ever SMA medicine called SPINRAZA® (nusinersen) in Australia in June 2018, that tragic statistic is no longer true.

However, it is unacceptable that early diagnosis of SMA depends upon where you live. Early diagnosis is key to maximising the benefit of current treatment options and slowing disease progression. SMA is a prime example highlighting the difference in mortality and mobility outcomes of SMA babies born in different States and Territories due to the differing availability of SMA testing in newborn screening (NBS) across States and Territories.

It is recommended that once a disease is available on the national panel for NBS, that funding be made available to ensure all States and Territories can immediately implement testing for the disease. The Commonwealth should consider a nationally uniform approach to funding and implementing NBS.

Furthermore, as technology advances, personalised medicines will become more common and access to genomic screening to support early diagnosis is vital for a precision medicine approach to health care. Currently such access is variable and routine access to affordable genomic testing remains elusive for many families. Genomic screening needs to have a uniform approach and also be made affordable

and accessible for patients. Genomic testing will become a central pillar for patient diagnosis and this needs to be recognised now and funded appropriately.

Budget Ask

- Funding be made available to ensure that the States and Territories can immediately test for rare diseases once a disease is included on the national panel for NBS.
- A uniform approach and permanent funding should be provided to ensure genomic testing becomes a central pillar for patient diagnosis in the Australian healthcare system following the success of the GHFM.

Registries

The rare disease community is by nature small, and so the management of clinical and patient driven registries are vital and becoming increasingly more accessible and cost-effective due to online access. Besides the immense scientific advantage of collecting a real-world evidence base, it also creates a sense of belonging for patients, and provides a sense of worth for patients to know that they can help progress science and innovation by consenting to sharing their health data.

Funding

For example, in June 2018, Biogen introduced the world's first ever SMA treatment called SPINRAZA in Australia. Since registration, there has been a significant collection of clinical trial data and real-world data (RWD). To further support the RWD already collected for adults with SMA, Biogen is the sole sponsor of an Australian SMA disease-based registry that can be used by researchers to study the trajectory of the disease and the clinical effectiveness of all SMA therapies. Biogen has committed more than 1 million dollars over three years for this project. Commencing in its updated version in December 2019, this registry makes available to researchers, important information which can be used to assess how Australian people with SMA are improving.

The SMA Registry is part of the Australian Neuromuscular Disease Registry (ANMDR) which aligns with international guidelines and expectations, so it can be combined with international datasets. ANMDR collects important medical information from adults and children across the country to improve the understanding of neuromuscular disease and aims to aid the development of new medicines. ANMDR is hosted by the Murdoch Children's Research Institute (MCRI) in Melbourne. The SMA registry now has more than 130 participants, of which approximately 50% represent adults with SMA, many of which remain untreated due to the current Pharmaceutical Benefits Schedule (PBS) restrictions that discriminate according to age – meaning only those [children with SMA] who commence SPINRAZA before their 19th birthday can have access. Anyone 19 years and older cannot access subsidised treatment via the PBS simply due to their birthdate.

Placing the needs of patients first, in May 2021, Biogen initiated a free of charge pathway so adults with SMA could access SPINRAZA on compassionate grounds. To date many people have accessed this pathway with many on treatment for more than six months.

While the SMA community is well serviced due to generous donations by Biogen, it is recommended that as a principle, dedicated government funding of registries would enable other rare disease communities to build capacity that can assist to develop clinical research, information, and advocacy campaigns, along with patient support initiatives.

Lack of coordination

In Australia, data for most rare diseases is not captured in either health information systems or registries and there is no coordinated strategy to collect, measure, build and translate data that does exist.[viii] To maximise the potential of this health data for the rare disease community, Australia needs a national, coordinated, and systematic approach to the collection and use of rare diseases information – this is an opportunity for the Government to take a leadership position as a coordinator.

For many people, these changes for genetic testing and registries would:

- Improve time to diagnosis saving lives and slow disease progression
- Provide equity for Australians living with rare diseases and better inform their decision making
- Improve and support a personalised approach to accessing therapies
- Strengthen cooperation and connections between industry, researchers, clinicians, patient associations/foundations and people living with rare diseases
- Support clinical research
- Reduce burden of disease costs to individuals and their families
- Improve productivity and reduce economic costs to Governments.

Budget Ask

- Appropriate public funding be made for rare disease registries that would aid in the collection and analysis of data that will support better research, clinical and diagnostic decision making for those afflicted by a rare disease.
- To enable coordinated and collaborative data collection to facilitate the cumulative knowledge of rare diseases, the Federal Government should develop a national approach to person-centred rare disease registries to support national standards, best practice, and minimum data sets.

Appendix 1 –*The Future of Alzheimer's Disease* White Paper

Link: https://www.biogen.com.au/en_AU/stories/future-of-alzheimer.html

Appendix 2 – *The Economic and Societal Cost of Alzheimer's Disease in Australia, 2021-2041* (draft)

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[i] Dementia Australia, Dementia prevalence data, accessed 13 January 2022, <https://www.dementia.org.au/information/statistics/prevalence-data>

[ii] Australian Department of Health, How to do the bowel screening test, accessed 27 January 2022, <https://www.health.gov.au/initiatives-and-programs/national-bowel-cancer-screening-program/getting-a-bowel-screening-test/how-to-do-the-bowel-screening-test>

[iii] Australian Institute of Health and Welfare, Dementia in Australia, 20 September 2021, <https://www.aihw.gov.au/reports/dementia/dementia-in-aus/contents/aged-care-and-support-services-used-by-people-with-dementia/residential-aged-care>

[iv] Brown LJ., Li J. and La HA (2022). The Economic and Societal Cost of Alzheimer's Disease in Australia, 2021-2041. NATSEM, University of Canberra, Canberra. (draft version in Appendix 2, final version to be released on 9 February 2022)

[v] Australian Department of Health, Genomics Health Futures Mission, accessed 27 January 2022, <https://www.health.gov.au/initiatives-and-programs/genomics-health-futures-mission>

[vi] Australian Department of Health, What we're doing about rare diseases, accessed 27 January 2022, <https://www.health.gov.au/health-topics/chronic-conditions/what-were-doing-about-chronic-conditions/what-were-doing-about-rare-diseases>

[vii] Australian Department of Health, What we're doing about rare diseases, accessed 27 January 2022, <https://www.health.gov.au/health-topics/chronic-conditions/what-were-doing-about-chronic-conditions/what-were-doing-about-rare-diseases>

[viii] Rare Voices Australia, Research and Data, accessed 27 January 2022, <https://rarevoices.org.au/wp-content/uploads/2020/09/ResearchandDataSummary.pdf>