3 March 2015

Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern

Re: Consultation: Regulation of autologous stem cell therapies: Discussion paper for consultation

MS Australia welcomes the opportunity to make a submission to the Therapeutic Goods Administration (TGA) regarding the regulations surrounding the provision of stem cell therapies in Australia and we support the views of our partner organisation MS Research Australia on this issue.

As the national peak body for people with MS we are proud to advocate on behalf of our member organisations and the MS community. There are currently more than 23,000 people living with MS in Australia with an additional 1000 diagnosed every year. MS can be a particularly debilitating disease with 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.

The challenges faced by people with MS can be significant and can have a devastating impact on their families and the wider community. Relapses can result in short term or long term disability, resulting in the need for physical and/or psychological care and support, medical investigations, treatments and hospitalisation.

These symptoms, or the gradual progression of the disease through relapses, mean that the many people with MS are unable to retain their employment. In fact, people with MS are more likely to be unemployed than those with any other chronic disease. This contributes to an increasing economic burden of MS on the rest of society. Currently, the economic cost of MS to the Australian community is estimated to be around $1.04 billion a year. Being able to better manage and limit the frequency and impact of relapses can help alleviate the burden of MS on the community and the individual.

That is why we advocate for greater accessibility to safe and effective forms of treatment for people with MS. There is certainly growing interest in Australia regarding stem cell treatment for MS and there are currently two stream of treatment offered.

Autologous Haematopoietic Stem Cell Transplant (AHSCT)

There has been considerable patient and media interest in Autologous Haematopoietic Stem Cell Transplant (AHSCT) as a form of treatment for MS. Currently, the treatment is considered experimental and is offered by a limited number of hospitals across the country, for a small percentage of people with severe forms of MS that do not respond to licensed MS therapies.

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MS Australia would welcome a regulatory environment that encouraged further research in this field, under controlled circumstances so that researchers and clinicians across the country can explore the full potential of this treatment and its application for people with MS. As stated in the TGA's discussion paper, AHSCT for the treatment of cancer is not included in the current regulatory review. MS Australia would like to suggest that AHSCT for the treatment of certain autoimmune disorders could also be added to the list in Attachment 1, to enable the continued evaluation of AHSCT as a potential treatment for severe autoimmune disorders.

Other autologous stem cell therapies

Distinct from AHSCT, MS Australia is particularly concerned over the emergence of unregulated providers of unproven stem-cell based treatments, such as therapies making use of mesenchymal stem cells derived from blood, fatty tissue and other sources. There are a growing number of private practitioners and clinics across Australia and internationally that have been offering this as a treatment for people living with MS.

The treatments are costly and to date there is very limited published evidence to prove these therapies are safe and effective. Facilities offering these treatments frequently revert to emotional marketing strategies utilising 'personal testimonies' and promoting 'miracle cures' for many conditions including MS.

For these reasons, MS Australia would advocate that these autologous stem cell therapies be regulated under Option 5 (Regulate under the Act as Class 2, Class 3 or Class 4 biologicals) as outlined in the discussion document, and would welcome greater TGA scrutiny of this area of stem cell treatment in particular.

Preferred option

Option 5 is the only viable option to ensure people with MS are protected and have access to proven treatment options. It will provide all necessary requirements for manufacturing standards and licensing, long term safety and adverse event reporting. It will prevent advertising to the public, but will not prevent patients from accessing treatments during the clinical trials process, or once approved, via referral following informed discussion with their treating physicians.

It would also help to foster collaboration and innovation amongst researchers and institutions which could expedite vital information in a safe manner, regarding the suitability of autologous stem cell therapies for people with MS and help to make it more widely accessible at facilities across the country.

Yours sincerely,

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MS Australia