



The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC23-010446

Ms Lucy Haslam
Co-Founder - United in Compassion Ltd
Co-Founder & Chair - Australian Medicinal Cannabis Association
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Dear Ms Haslam

Thank you for your correspondence of 15 May 2023, and your earlier correspondence of 29 November 2022, regarding matters discussed at our meeting on 22 November 2022; in particular, the request for seed funding for the COMPASS Compassionate Access Scheme, ahead of the Parliamentary Friends of Medicinal Cannabis meeting in Canberra on 14 June 2023. I apologise for the delay in responding.

I note the growing interest in utilising medicinal cannabis products for the management of several debilitating and chronic medical conditions among Australian prescribers and patients and acknowledge your contribution, as part of the Australian Medicinal Cannabis Association (AMCA), to Australia's expanding cannabis industry.

I understand that several companies, like AMCA, are providing medicinal cannabis products under a compassionate access scheme for those least able to afford them under the existing regulatory schemes. Each company can offer compassionate access schemes for patients, should they wish to do so.

Whilst the Australian Government is supportive of the COMPASS Compassionate Access Scheme, I have been advised that the Department of Health and Aged Care, which includes the Therapeutic Goods Administration (TGA), is not able to fund such programs at this time.

Medicinal cannabis products are regulated as medicines in Australia to enable them to meet community expectations of high standards of safety and quality as for other medicines, and I am confident that Australian patients are accessing medicinal cannabis products in a timely manner under the current access schemes. The rate of growth in patient numbers has been consistent and substantial with more than 660,000 prescriptions written for medicinal cannabis products in the period to the end of May 2023.

However, the cost of medicinal cannabis products continues to be a significant access barrier for many patients in Australia. As such, the TGA strongly encourages discussions with prospective sponsors about the regulatory process for medicinal cannabis products so that products can be included on the Australian Register of Therapeutic Goods (ARTG) as prescription medicines or as Schedule 3 cannabidiol preparations.

As you are aware, under legislation, once a sponsor's product is included on the ARTG, they can apply to have it listed on the Pharmaceutical Benefits Scheme, which could allow subsidised access for consumers.

The TGA has delivered a range of educational activities to help stakeholders understand their regulatory obligations under the *Therapeutic Goods Act 1989*. This includes the publication of guidance material about the advertising and lawful supply of medicinal cannabis products. Further information is available at www.tga.gov.au by entering the search term 'Medicinal cannabis: Information for sponsors and manufacturers'.

Thank you for writing on this matter.

Yours sincerely



Mark Butler

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