Australian Medicinal Cannabis Association

The Hon Mark Butler
Minister for Health and Aged Care
Parliament House
Canberra
ACT 2600

Ref No: MC23-010446

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Dear Mr. Butler,

We were very surprised and disappointed to receive your letter dated 13 June 2023 informing us that you and your Department have declined to fund the AMCA COMPASS compassionate access scheme.

Specifically, your letter states that you *"have been advised that the Department of Health and Aged Care, which includes the Therapeutic Goods Administration, is not able to fund such programs at this time".* That advice does not accord with the discussion we had with Associate Professor John Skerritt and Mr Avi Rebera at the UIC Symposium in May 2022, during which we explained our proposed model for the COMPASS Scheme and its objectives. Professor Skerritt congratulated us on the work we had done, lauded the proposed model and encouraged us to present it to the Australian Advisory Council on the Medicinal use of Cannabis (AACMC) which we did on 9th September 2022. He also suggested that we liaise with you directly on the issue of funding, on the basis that such a decision would need to be made by the Minister himself.

The receipt of your letter the day before we and our colleagues presented to the Parliamentary Friends of Medicinal Cannabis was especially surprising. From our meeting with you when we visited Canberra in November 2022, we understood that you accepted the need for a compassionate access scheme. As Recommendation 19 from the Senate Inquiry into Barriers to Patient Access stated:

5.103 The committee recommends that, until medicinal cannabis products are subsidised though the Pharmaceutical Benefits Scheme, the Australian Government:

- **investigate the establishment of a Commonwealth Compassionate Access Subsidy Scheme for medicinal cannabis, in consultation with industry and based on the best available evidence of efficacy for certain conditions; and**
- **encourage all states and territories, through the COAG Health Council, to expand the provision of their own Compassionate Access Schemes to patients requiring treatment with medicinal cannabis.**

As you will be aware, the possibility of medicinal cannabis products being subsidised through the Pharmaceutical Benefits Scheme (PBS) is highly unlikely for medicinal cannabis products that are not registered in the Australian Register of Therapeutic Goods (**ARTG**).

Even though there are companies in the sector who appear to be working towards ARTG registration, with several clinical studies underway, the cost of entering the sector has been (and remains) extreme, with cultivators and producers required to meet security levels on a much higher scale than that required for other medicines (*e.g.* opioid medicines). This has left most companies with limited or no funding for research projects, including the type of clinical trials required to demonstrate safety and efficacy, and then to also meet the requirements (cost minimisation or cost effectiveness) for products to be listed on the PBS. It is likely, then, that almost all medicinal cannabis products will never be listed on the PBS, will remain expensive and, in many cases, will be out of reach of Australian patients in need.

Referring to the Hansard recording of your 2021 speech to the House of Representatives on the Narcotic Drugs Amendment (Medicinal Cannabis) Bill 2021 Second Reading on Wednesday, 24 February 2021, you appear to have recognised this issue in the context of the down-scheduling of cannabidiol to Schedule 3, but the issue is relevant for all medicinal cannabis products:

> *"To get a product approved and put onto the ARTG …….a company is going to have to put a product to the TGA for assessment. That will, under the existing framework, for very good reason, require substantial evidence of the efficacy and safety of that product. That potentially takes years of evidence gathering and clinical trials and many, many dollars, sometimes running to tens of millions of dollars, by the proponent company. So it is difficult to see products being approved by the TGA any time soon that will actually make that down-scheduling decision by the TGA something of real moment or of practical application for patients. I make the point that the TGA has been trying to make some changes that will accommodate the needs of patients, but it hasn't really been able to do anything that I think will have a real-world impact for those many hundreds of thousands of Australians who are using these products every day."*

> *"This does come with substantial cost to the patients. Not only are these products not on the ARTG; ipso facto they are obviously not on the PBS. The patients are paying for these products out of their own pocket. In that same study I described, in the Australian Prescriber, it was indicated that the average cost is somewhere between $5 and $15 per day for patients accessing medicinal cannabis products through the Special Access Scheme. That is an average. If you have conditions, such as epilepsy, that require relatively high doses of CBD, or medicinal cannabis, in your therapeutic good, then you are paying substantially more than $15 per day, day in, day out. This is a very substantial impost on families and patients across the country."*

You also said in your speech that:

> *"less than four per cent of …. Australians are obtaining their medicinal cannabis product through legal pathways. That is a major concern. More than 96 per cent of the hundreds of thousands of Australians using medicinal cannabis are obtaining those products other than through the legal pathways established by this legislation, by the originating 2016 legislation and by the general TGA framework."*

More than two years on from your speech, although the Special Access Scheme and Authorised Prescriber pathways have provided legal pathways for Australian patients to access medicinal cannabis products, the cost to patients now often exceeds the estimates you provided above. This is especially so for patients requiring high doses of cannabidiol *e.g.* children with intractable epilepsy conditions such as Dravet's syndrome. For this reason, up to 50% of eligible patients in need in Australia are

accessing their supply through illegal pathways – the issue, therefore, is no longer due to lack of access pathways; it is now an issue of affordability.

In your 2021 speech you also said:

> *"The concern that this provision is mere symbolism and the concern that this legislation really just deals with some worthy but pretty modest streamlining of measures that were imposed by the original legislation upon industry participants is not just a view of the opposition. It's been a view expressed by a number of patient advocate groups through the McMillan review process and as this bill has been out for consultation.* ***Mills Oakley****, for example, said in its submission, 'In our view, the most significant disappointment in the bill is its lack of real measures to improve patient access to affordable and domestically sourced medicinal cannabis.' The well-known patient advocacy group* ***United in Compassion*** *was a little bit more forthright in its view, indicating: 'From a patient's perspective, it'—the framework from the 2016 act—'has been a catastrophic failure. The illicit market is booming. Patients are still being locked up because they cannot afford or achieve legal access.' I think I'm right in saying these are concerns that all members of this place, on both sides of the House, would be receiving from patients across the country and across a very diverse group of patient cohorts."*

The quotes from Mills Oakley and United in Compassion were made by the very two individuals who went on to co-found AMCA and who are the undersigned of this reply to your letter. We are not lightweights in the medicinal cannabis industry, having been key participants in the sector for nearly a decade, and both of us, and our organisations, are highly respected in the sector. We organised the meeting with you last November to outline a proposed National compassionate access scheme that would, essentially, do the work that the Senate Inquiry recommended the federal and state/territory governments do; that is:

1. establish a Commonwealth Compassionate Access Subsidy Scheme for medicinal cannabis, in consultation with industry and based on the best available evidence of efficacy for certain conditions; and
2. encourage all states and territories, through the COAG Health Council, to expand the provision of their own Compassionate Access Schemes to patients requiring treatment with medicinal cannabis.

As you would be aware, a Commonwealth national compassionate access scheme has still not been established (or even planned), nor are any of the states or territories providing compassionate access schemes. AMCA approached you with such a scheme already planned and supported by companies in the sector willing to provide free-of-charge supply for the scheme. As mentioned earlier, the TGA has also fully supported the plans for this scheme.

In your letter, you stated:

> *"I understand that several companies, like AMCA, are providing medicinal cannabis products…." And that "Each company can offer compassionate access schemes for patients, should they wish to do so."*

This appears to be passing on the responsibility of a compassionate access scheme to the few companies interested or in a position to do so, and does not provide a national approach that ensures

equity of access rather than favouring patients who live in the "right place" or "have the right contacts". This is not as recommended by the Senate Inquiry and continues to shirk the responsibility of the sitting Federal Government.

AMCA is also not, as you suggested in your letter, a medicinal cannabis company. It is a not-for-profit organisation representing the sector, from patients to industry. AMCA is in a unique position to administer a national compassionate access scheme that can replace the need for federal, state or territory governments to do so, at a substantially lower cost. COMPASS has been designed as an equitable, independently-run, national scheme, accessible through each patient's own clinician instead of the decisions of a medicinal cannabis company. All that is required is modest seed funding to establish the scheme ($800,000k), with no plans for AMCA to request any further funding from the Federal Government.

AMCA is ready to initiate this scheme and to do so would be to achieve what has still not been actioned three years on from the Senate Inquiry recommendations. We would be pleased to run the scheme on behalf of the Federal Government, so that the comments you made with regard to the previous Liberal government will not be reflected back at your party now that it is in the seat of power:

> *"There still remains much to be done in the emerging area of the therapeutic use of medicinal cannabis. Frankly the government doesn't appear to be doing much in that area, particularly in the area of improving access for patients across the country to safe,* ***affordable*** *and effective medicinal cannabis products. The government has been dragging its feet for years in this area, most notably when it continued to resist the opposition's calls in the other place for a Senate inquiry into barriers against patient access to those safe, effective and* ***affordable*** *medicinal cannabis products."*

We, and the Parliamentary Friends of Medicinal Cannabis with whom we met the day after receiving your letter), are at a loss to understand why our modest request ($800,000 over 3 years) for seed funding to kick-start the national compassionate access programme has been declined.

In view of the admission in your letter of 13 June that *"…the cost of medicinal cannabis products continues to be a significant access barrier for many patients in Australia."* and the statement at the end of your 2021 speech that *"As Olivia Newton-John said last year: "Why not make it easier for people to get, particularly those suffering with pain? Why not make their lives a bit easier?"*, we ask that you will reconsider our request so that this unique and equitable scheme can begin without further delay.

Yours sincerely,

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