Australian Medicinal Cannabis Association

Submission for Inquiry into Improving Access to Medicinal Cannabis Bill 2023

(*A Bill for an Act to amend the law relating to the regulation of products made or that contain cannabis, and for related purposes*)

by the AUSTRALIAN MEDICINAL CANNABIS ASSOCIATION

Introductory comments

The Australian Medicinal Cannabis Association (AMCA) is an ASIC- and ACNC-registered association representing more than 150 stakeholders from the breadth of the medicinal cannabis sector, including cultivators, manufacturers, importers, distributors, researchers, medical practitioners, nurses, pharmacists, patients and their carers, consumers and broader advocacy groups.

AMCA welcomes the opportunity to make a submission to the Inquiry into Improving Access to Medicinal Cannabis Bill 2023 (the "**Bill**").

Response to the proposed Bill

Since it was established in 2020, AMCA has sought to address challenges facing the medicinal cannabis sector, many of which were highlighted by the 2019 Senate Inquiry into Barriers to Patient Access to Medicinal Cannabis (that reported in March 2020).

As most of the recommendations from that Inquiry have still not been actioned, including those seeking to address the affordability of medicinal cannabis for patients in need, AMCA was encouraged to see Senator Pauline Hanson's proposed Bill. However, **although we applaud Senator Hanson for her proactive effort to address key issues remaining more than 7 years after legalisation**, concerns raised by the co-founder and Company Secretary of AMCA, Dr. Teresa Nicoletti (an experienced and accomplished lawyer working in this sector and leading a team at Mills Oakley law firm in Sydney) have highlighted some key points that may negatively impact the objectives of the Bill.

The key points of concern for AMCA, as raised in Dr. Nicoletti's analysis of the Bill, are listed below:

1. The regulatory schemes currently in place for unregistered medicinal cannabis products, the Special Access Scheme-B (SAS-B) and Authorised Prescriber Scheme (APS), although not ideal, do enable the supply of medicinal cannabis products as unapproved goods in circumstances where safety and efficacy have not been properly established, irrespective of whether the medicinal cannabis product is Schedule 4 or Schedule 8.

2. The numbers of patients legally accessing medicinal cannabis through the SAS-B and APS pathways since their establishment for medicinal cannabis in 2016 (1,157,195 patients under the APS and 344,695 approvals under SAS-B) illustrate that patients are able to access medicinal cannabis through this route.

3. Most medicinal cannabis products (except for Sativex and Epidyolex) still do not have sufficient efficacy and safety data to enable them to be registered in the Australian Register of Therapeutic Goods (**ARTG**), such data also govern eligibility for listing on the Pharmaceutical Benefits Scheme (PBS).

4. The randomised controlled clinical trials needed to generate the data required for ARTG registration and PBS listing would, in part due to years of prohibition, be extraordinarily expensive and lengthy. ARTG registration requires complex dossiers of chemistry, pre-clinical, clinical and manufacturing data, and listing on the Pharmaceutical Benefits Scheme (PBS) additionally requires cost-effectiveness or cost minimisation data comparing the product seeking listing with a currently listed product(s) for the same indication.

5. It is therefore unlikely that most medicinal cannabis products will ever have the data required to be listed on the PBS, and we agree with Dr. Nicoletti that this will not be facilitated by amendments to the Poison Standard. Down-scheduling medicinal cannabis from S8 to S4 will also not facilitate the listing of medicinal cannabis products on the PBS.

Cost and affordability remain the main barriers to access to medicinal cannabis for most patients in need. In view of the above points, the proposed amendments of the Bill to the Poisons Standard, although proposed with good intent, will not address the main aim of the Bill of **Improving Access,** because they will not enable PBS listing, nor address the key barrier, which is the cost to patients.

AMCA believes that addressing cost and affordability will be best met by:

- finding alternative funding, or subsidising, of medicinal cannabis products; and
- addressing the high level of price gouging and closed-loop arrangements currently evident in the sector which are significantly increasing costs in the supply chain for which patients are ultimately paying higher than necessary prices.

We would like to add that two of the other key barriers for eligible patients being able to gain the medical benefits of medicinal cannabis are:

- current State and Territory driving laws which unfairly discriminate against patients driving on any legally prescribed detectable level of THC (tetrahydrocannabinol) whilst other similar drugs (*e.g.* opioids and benzodiazepines) are not included in police roadside tests; and
- many legally prescribed patients losing their jobs due to stigma remaining with many employers.

AMCA joins with Dr. Nicoletti in encouraging the government to engage with our members and the wider medicinal cannabis industry to develop policies and legislative changes that will better address cost and affordability, the key barriers to access for medicinal cannabis patients.

We would welcome the opportunity to appear before the Committee, but are satisfied that Dr. Nicoletti, through Mills Oakley, will provide an expert opinion to the Committee that will reflect the concerns of AMCA.

If you have any questions or require further information, please do not hesitate to contact the undersigned.

Yours sincerely,

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AMCA
Australian
Medicinal Cannabis Association