3 May 2023

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

via: Submission Upload

RE: Submission to the inquiry for the Improving Access to Medicinal Cannabis Bill 2023 (the Bill)

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to provide a submission to the Community Affairs Legislation Committee for consideration for their report into the above Bill.

MCIA believes that the intent of the above Bill to improve access for patients and thus alleviate pressures on both patients, doctors and pharmacists, is commendable. However, MCIA does not believe that the Bill as it stands addresses the key impediments to patient access.

About MCIA

MCIA is the peak industry organisation for Australia's medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and manufacturing and interaction with patients, the medical profession and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients. MCIA provides stewardship for an economically sustainable and socially responsible industry that is trusted and valued by patients, the medical community and governments.

While MCIA is supportive of a regulatory framework that enables the development of a medicinal cannabis industry in Australia and access for patients to this product that has potential to positively contribute to a broad range of conditions, the current system does require continual streamlining, and example of this has been the TGA moving some cannabis medicines to the established history of use pathway for doctors to prescribe.

MCIA recognises and promotes the need for further improvements to the regulatory system to enable licence holders to operate and facilitate patient access to timely, cost effective and quality Australian product.

Key issues with the *Improving Access to Medicinal Cannabis Bill 2023 (the Bill)*

Amendment of the Poisons Standard

The Bill looks to amend the *Therapeutic Goods (Poisons Standard—February 2023) Instrument 2023* (the Poisons Standard). The Poisons Standard is made under section 52D(2)(b) of the *Therapeutic Goods Act 1989* (the *Act*), and the Secretary may exercise a power under 52D(2) of the *Act* on the Secretary's own initiative or following an application under section 52EAA of the *Act*. Thus, the *Act* establishes a clear pathway for the application to amend the Poisons Standard.

Moreover, under section 52E of the *Act* the Secretary is required to take certain matters into account when exercising a power under section 52D(2), being (where relevant):

a) the risks and benefits of the use of a substance;

b) the purposes for which a substance is to be used and the extent of use of a substance;

c) the toxicity of a substance;

d) the dosage, formulation, labelling, packaging and presentation of a substance;

e) the potential for abuse of a substance;

f) any other matters that the Secretary considers necessary to protect public health.

There are also further requirements under this section 52E for compliance with guidelines by the Australian Health Ministers' Advisory Council, and regard to recommendations or advice of the Advisory Committee on Medicines Scheduling (ACMS) or the Advisory Committee on Chemicals Scheduling (ACCS).

MCIA has no comment on the validity of the legislative approach proposed under the Bill to amend the Legislative Instrument, the Poisons Standard. However, MCIA does believe that the process currently in place for application to amend the Poisons Standard provides a well established and rigorous process of expert review by the Joint ACMS-ACCS, that is both transparent and assesses the broad risk to patients and the community under an appropriate framework.

Scheduling of Cannabis, Tetrahydrocannabinol

MCIA believes there is an opportunity for stakeholders to engage with the Joint ACMS-ACCS and/or Secretary with regards to scheduling considerations for medicinal cannabis which impact the development of medicinal cannabis as a therapeutic good in Australia this should include State and Territory health departments.

An example of recent decisions regarding scheduling is the unsuccessful application to down-schedule cannabis and THC to Schedule 7 for the purposes of research. It is an idiosyncrasy of the current scheduling that research to develop medicinal cannabis goods (other than pure CBD), must be done under the constraints of Schedule 9 Prohibited Substances, but these same goods may be given to a patient under special access provisions as a Schedule 8 Controlled Drug.

In the August 2022[1] Notice of Interim Decision regarding an application for Schedule 7 scheduling for research, it was noted that the toxicity of cannabis and its extracts is *not* consistent with Schedule 7 factors. This is correct - in fact the toxicity of cannabis and its extracts sit below the bar established for dangerous poisons under Schedule 7. As noted by the ACMS-ACCS, the substance is "Low toxicity to adults, some toxicity to children".

In the subsequent November 2022 Notice of Final Decision to Amend (or not amend) the Poisons Standard[2] it was noted that "given the current evidence for the benefits of the substance weighed against the risk of diversion, abuse and misuse, and Australia's obligation when a substance is included in Schedule IV to the United Nations Single Convention on Narcotic Drugs, 1961, [the Secretary's] current view is the substance is better aligned with the Schedule 9 factors."

This reasoning is worth exploring in the broader context of scheduling of medicinal cannabis, even given the focus on research in this specific example.

[1] https://www.tga.gov.au/resources/publication/scheduling-decisions-interim/notice-interim-decisions-proposed-amendments-poisons-standard-acms-37-accs-33-joint-acms-accs-30-march-2022

[2] https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-acms-37-joint-acms-accs-30-accs-33

It is accepted that cannabis and THC are less toxic than the bar set for Schedule 7 Dangerous Poisons. In denying rescheduling, there is a heavy emphasis on the lack of "current evidence for the benefits of the substance" – yet impediments to undertaking research to develop evidence, such as the heavy constraints placed on dealing with substances classed as Schedule 9, are maintained. Equally, there is a heavy emphasis on "risk of diversion, abuse and misuse", which overlooks the entirety of the regulatory framework which puts significant controls around this. At its simplest, medicinal cannabis must be grown, manufactured or imported into Australia in order to be used for research or provided to a patient, and each of these sources have a strict framework requiring the responsible entity to have control of supply lines. This significantly decreases risk of diversion independent of controls in place through poisons scheduling.

A potential approach could be for a more comprehensive review of the scheduling of cannabis be undertaken by TGA to address the issues above, and also give consideration to the option of Schedule 4 Appendix D drugs - Prescribed restricted substances[3]. Such a review, utilising data generated via the SAS pathway, could help develop a solution that provides a more suitable scheduling but which also complies with the risk of diversion through sufficient requirements in relation to storage and record keeping.

This idiosyncrasy in scheduling between research and patient use also existed for cannabidiol (CBD), until redressed in February 2021 when the Schedule 4 listing for CBD was expanded to include CBD use for analytics and research purposes.

Thus, MCIA is not supportive of amending the Poisons Standard as it pertains to medicinal cannabis by bypassing expert review by the Joint ACMS-ACCS and decision by the Secretary. MCIA is ,however ,highly supportive of having all stakeholders engage with the TGA to discuss and address perceived risks associated with re-scheduling, resulting in the TGA spearheading an application to amend the Poisons Standard, in a manner similar to their application for the Schedule 3 listing for CBD that the MCIA supports.

Removing the need for special access pathways

The MCIA has been very supportive of the actions taken by Federal and State governments to harmonise the process nationally for patient access – removing many of the state-based requirements introduced specifically for medicinal cannabis. Moves to streamline the special access processes have also been welcome and should continue.

MCIA is also supportive of the changes made by the TGA in requiring that medical cannabis be supplied under GMP. This coming into effect in July 2023. This move is a further evolution that cannabis medicines supplied in Australia will meet the strict requirements of safety required by the TGA.

While recognising that the Authorised Prescriber (AP)and Special Access Schemes (SAS) add a burden to prescribers and therefore impact patients, we caution that in seeking to give primacy to the doctor/ patient relationship in the manner outlined in the Bill, there may be unintended, negative consequences for both the doctor and the patient. These primarily flow from the lack of safeguards that are provided through the therapeutic good registration process.

Summary

MCIA welcomes the opportunity to provide this submission to the Community Affairs Legislation Committee into the Bill. MCIA believes that the intent of the above Bill to improve access for patients and thus, alleviate pressures on both patients, doctors and pharmacists is commendable. However, MCIA does not believe that the Bill as it stands addresses the key impediments to patient access, and that there may be unintended, negative consequences for both the doctor and the patient. These primarily flow from the lack of safeguards that are provided through the therapeutic good registration process.

[3] https://www.health.nsw.gov.au/pharmaceutical/Pages/sch4d.aspx

MCIA supports the position that facilitating registration of medicinal cannabis is paramount. However, the pathway to registration is unclear, given that medicinal cannabis medicines differ in some key aspects from new chemical entities that predominantly traverse the registration pathway. Given the significant investment required to sponsor a therapeutic good through registration, key issues for the sector relate to the clarity of the requirements as whole plant medicines, and the degree of protection afforded to the sponsor regarding the registration of any cannabis medicine.

As such, MCIA supports continuing improvements in patient access under the SAS scheme.

Yours sincerely

Rosemary Richards
Executive Manager