MedReleaf
AUSTRALIA
THE MEDICAL GRADE STANDARD™

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ODC Licensee: Indica Industries Pty Ltd

Indica Industries Pty Ltd t/as

MedReleaf Australia

(ABN 25611697762)

Submission: Improving Access to Medicinal Cannabis Bill 2023

May 2023

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About MedReleaf Australia

MedReleaf Australia is licensed to cultivate and manufacture medical cannabis by the Federal Government's Office of Drug Control (ODC) and also holds licenses to import, export, wholesale and distribute medical cannabis products. Australian-owned and operated, the company is backed by more than 50 years of pharmaceutical and healthcare expertise, driven by Research and Development, and strives to make improvements to the health of Australian patients. Built to service the Australian medical industry, including doctors, pharmacists, and allied health professionals. MedReleaf is also licenced to supply medical cannabis medicines into New Zealand.

MedReleaf has a strategic and exclusive partnership with Aurora Cannabis Enterprises (NYSE|ACB. Our Queensland based company is currently importing and distributing the widest range of GMP medicinal cannabis products into the growing market in Australia.

MedReleaf Australia (MRA) is also a founding member of the Medical Cannabis Industry Association (MCIA) and supports the MCIA submission on this topic.

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

MedReleaf does not believe that the intent of the Bill that has been put forward is targeted towards improving access to medical cannabis for patients. It is our opinion that these suggested amendments still present key barriers that will continue to limit patient access.

The TGA has made structural improvements to the access pathways for Doctors and health care professionals to improve their ability to prescribe medical cannabis for those in need. Currently the TGA reports information on their website in relation to the Special Access Scheme (SAS) and Authorised Prescriber (AP) pathways and that data highlights the wide therapeutic use of medical cannabis across all ages of Australian patients.

Please refer to - TGA website

- Medicinal cannabis Special Access Scheme Category B data | Therapeutic Goods Administration (TGA)
- Authorised Prescriber Applications (health.gov.au)

A recent example of the TGA initiating prescribing improvements was the move of some cannabis medications to the Established History of Use pathway for Authorised prescribers. This has been a positive move, however more work is required to enable Doctors to assist their patients in a more timely manner to enable improved access.

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Key Issues

Down-scheduling of Cannabis, Tetrahydrocannabinol.

MedReleaf is of the opinion that the TGA and the Federal and State health departments have enough data from the SAS to make these scheduling changes, and supports the down scheduling of THC. We do note that the TGA has made a recent decision regarding the unsuccessful application to down-schedule cannabis and THC to Schedule 7 for the purposes of research.

In the August 2022 Notice of Interim Decision regarding an application for Schedule 7 scheduling for research (refer - 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, 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 such the TGA should take this into consideration and accept the suggestion in the bill to down schedule THC containing medicines.

Regarding the Scheduling of cannabis, in November 2021 MedReleaf also made a submission towards patient access improvements including down schedule for cannabis medicines to S4D (refer to The New Frontier - Delivering better health for all Australians – Parliament of Australia (aph.gov.au). A possible oversight in the current bill is to not consider the option of listing THC in the Schedule 4 Appendix D drugs - Prescribed restricted substances. MedReleaf does believe that S4D may be a more suitable schedule that complies with the risk of diversion as this still addresses and meets the storage and record keeping required for medical cannabis medicines by State Health Departments. If the decision is to be made to reschedule THC to Schedule 4 then S4D should be considered.

Note: Reference - A good overview of S4D can be found here - https://www.health.nsw.gov.au/pharmaceutical/Pages/sch4d.aspx

Improve prescribing pathways for Doctors - Removing the need for special access pathways.

MedReleaf is very supportive of the actions taken by Federal and State governments to harmonise the process nationally for patient access by removing many of the state-based requirements introduced specifically for medicinal cannabis. Those moves, designed to streamline the special access processes have been welcome and should continue to improve patient access via their health care professional and pharmacy.

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MedReleaf is a founding member of the peak industry body, the MCIA and is also supportive of the changes being made by the TGA requiring that all medical cannabis be supplied under GMP, which is coming into effect in July 2023. This move is a further evolution to ensure that cannabis medicines supplied in Australia meet the strict requirements of safety required by the TGA.

MedReleaf is of the view that the TGA Authorised Prescriber and Special Access Schemes add a burden to prescribers, pharmacies and as such also impact patient access to cannabis medicines.

MedReleaf suggests the following:

1) All Categories 1-5 of medical cannabis products be moved to the Established History of Use pathway. (Currently this only has a limited number of cannabis formulations allowed e.g oral doses for category 1-3). This would allow all Doctors to prescribe all formulations with a greatly reduced regulatory burden.
2) Move All cannabis medicines to SAS Category C pathway. As a notification pathway this would also suit the record keeping requirements of the INCB in conjunction with dispensed medicine records that State Government health departments obtain and can supply to the TGA and ODC.

or

3) Remove all Categories of medical cannabis products from the SAS.

MedReleaf also notes that as recently as May 2nd, 2023, the government has reduced the regulatory and prescribing burden on doctors for nicotine-containing products, allowing doctors easier access to clinically intervene in their patients' chronic health conditions. The government should consider enabling this for doctors that wish to prescribe medical cannabis as well.

MedReleaf continues to support the continuing improvements taken by the TGA in patient access of medical cannabis while under the SAS scheme but would support further amendments as suggested to allow improved access of the now proven safe use of medical cannabis for Australian patients.

Russell C Harding B.Pharm, B.HMS, MACP, MAICD.

Chief Executive Officer

MedReleaf Australia