MedReleaf AUSTRALIA

THE MEDICAL GRADE STANDARD™

GPO Box 2846, Brisbane QLD 4001 Australia
Phone 1300 096 611 - Fax 07 3892 6311

medreleafaustralia.com.au

ABN: 25611697762 ACN: 611697762
ODC Licensee: Indica Industries Pty Ltd

17 January 2020

Senator Rachel Siewert
Chair, Senate Standing Committees on Community Affairs – References Committee Membership
PO Box 6100
Parliament House
Canberra ACT 2600

To the Committee Secretary,

MedReleaf Australia is pleased to provide a submission to the inquiry into current barriers to patient access to medicinal cannabis in Australia.

Indica Industries Pty Ltd (t/as MedReleaf Australia) is federally licensed to cultivate and manufacture medical cannabis by the Government's Office of Drug Control (ODC). We are backed by more than 60 years of pharmaceutical and healthcare expertise, driven by research and development, and with a company vision to improve the quality of life of Australians.

We are currently importing medical cannabis oils, capsules and dried flower from our Canadian partner, Aurora Cannabis Inc, global leaders in medical cannabis. Our brands include MedReleaf, Aurora and CanniMed, which are available via Australian Pharmacies. We offer the largest range of medical cannabis products currently available in Australian Pharmacies, and note that Australian Doctors are increasingly prescribing medical cannabis after receiving TGA approvals for their patients many of whom are suffering debilitating pain from intractable diseases that have been unresponsive to more traditional pharmaceutical - based treatments.

Upon commissioning of our GMP-optimised indoor growing system – expected to take place later next year – we will manufacture Australian-produced medical cannabis products using the world's most advanced techniques. Our Australian manufacturing systems will emulate our systems in Canada, ensuring an uninterrupted supply of identical product once local production is introduced.

MedReleaf Australia is also a founding member of the Medicinal Cannabis Industry Australia (MCIA), and has contributed to the MCIA's submission to this committee and supports that submission as a member.

We have kept this submission brief and would invite any further questions if you would like more detail.

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Thank you and kind regards,

Indica Industries Pty Ltd

Signed: __ __

Russell Harding
Chief Executive Officer
MedReleaf Australia

MedReleaf Australia sees five main issues currently related to the access of medical cannabis in Australia:

1. Patient medicine subsidies are required
2. Growth of the illicit cannabis market
3. State health alignment
4. Driving laws need to be reviewed and amended
5. TGA approvals to move from product-specific to indication-specific – with all GPs classified as Authorised Prescribers (APs)

1. Patient medicine subsidies are required:

The complete lack of medicine subsidies in Australia for legal medical cannabis products is a significant barrier to patient access. This is causing legitimate patients to seek illicit and often unsafe cannabis for therapeutic use, in a genuine attempt to improve their or their family members' quality of life.

Medical cannabis is a complex medicine and comprises hundreds of phytochemical active compounds, each with a different influence on the body's endocannabinoid system. Among the cannabinoids, THC and CBD are the most widely studied to date, and provision within the Pharmaceutical Benefits Scheme (PBS) would need to accommodate this complexity. "Cannabinoids work synergistically with each other and/or with terpenes", an effect commonly termed the 'entourage effect'. This hypothesis is supported by findings that show that extracts of whole-plant cannabinoids are more efficacious than isolated, single cannabinoids, and supports the idea that there are additive therapeutic effects between the different compounds found in cannabis. Currently, the ARTG listing process uses an inappropriate and restrictive methodology to ascertain efficacy for whole-plant medicines. The result is a strong likelihood that none will make it through the process and ultimately achieve PBS listing.

The PBS should be a means by which patients access medical cannabis, which is required to meet high standards as an unregistered medicine. MedReleaf Australia supports this, which ensures the safe use of these medicines. However, there is ample evidence from other jurisdictions of the safety and efficacy of cannabis over many years. Thus, to improve accessibility, to move patients off opioids and reduce polypharmacy, MedReleaf Australia suggests that the Government should endeavour to move the SAS A- and SAS B-approved cannabis products onto the PBS, perhaps via an alternate ARTG category. In the meantime, we are supportive of the successful TGA SAS

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Portal process that is being well supported by the few motivated GPs but because of cost, is not assisting the majority of patients in need.

2. Growth of the illicit cannabis market:
The illicit or black market is thriving, as it has always done in Australia; however, with the current access arrangements in place, it is growing further due to the general public becoming more informed about medical cannabis.
This is worsened due to the relative inaccessibility of the medicine via their own Doctors, most of whom are only beginning their prescribing journey. Patients or their families are turning to what they consider to be the only solution – the illicit market.

Medical cannabis companies are therefore forced to compete with this alternative and cheap economy that uses illicit market prices for defective "medicine". Patients are still paying considerably more than a PBS-subsidised medicine via the illicit route. They are also taking many risks by not being able to appropriately manage their cannabis medicine – the dosages, efficacy, side effects, and the potential contraindications with other medicines that they may be taking concomitantly – all of which are usually managed by their Doctor and Pharmacist, who can titrate the dosage or change the medicine as appropriate. The greatest risk, however, is not knowing what they are taking, and what contaminants are in their so-called "medicine". Safety is now linked to price – an increasing health risk as patients seek this medicine.

3. State health alignment:
There should be no barrier at a State level for the approval of medical cannabis if approved by the TGA. We refer you to the Department of Health Submission in relation to the current State approval pathways. Patients in several states are still required to seek specialist approvals over their own doctors' ability to prescribe for their own patient. The complex nature of this arrangement is causing the patients to directly seek illicit cannabis.

4. Driving laws need to be reviewed and amended:
Current drug driving laws as they relate to cannabis across Australia are considered a significant barrier to legitimate patient access in their current format and need urgent review. Other more-potent scheduled medicines that are prescribed are not tested for on roadside drug tests, yet we have Australians driving vehicles and operating machinery while taking those medicines. THC is a medicinal compound; therefore, THC should be removed from roadside test protocols. In addition to this is the patient-reported information that the Sativa cultivar actually improves patients' alertness. Patients that hold and present their TGA approval documents should be allowed to drive in the same way as some other medicines such as dexamphetamine for treating ADHD, which can provide a positive test for amphetamines via roadside testing.

5. TGA approvals to move from product-specific to indication-specific – with all GPs classified as Authorised Prescribers (APs)
Noting that most GPs are not proceeding to AP accreditation due to the efficiencies of the SAS Portal, we propose an amendment to streamline Doctor Submissions and, in turn, reduce the administrative burden for both Doctors and the TGA.

Current TGA Approval procedures should be re-evaluated and amended to the following:

- For each patient, the Doctor applies to the TGA for approval of supply of medical cannabis for *one particular indication* (e.g., chronic non-cancer pain)

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- The Doctor is then able to prescribe any unregistered medical cannabis product under the one single approval
- A report is sent weekly/monthly to the TGA outlining the products prescribed under each approval number
- Patients could have more than one approval for multiple conditions (if necessary).

END

Thank you again for your consideration of this submission.