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Submission to the Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia

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1.0 About FreshLeaf Analytics

FreshLeaf Analytics, a division of Southern Cannabis Holdings, is a professional services firm providing market intelligence and strategic consulting to international and domestic medical cannabis companies.

FreshLeaf Analytics has deep subject matter expertise regarding patient access in Australia including patient access pathways and forecasts; acquisition and attrition rates; treatment practices and doctor/patient behaviour; product availability and pricing, and medical cannabis policy.

We regularly speak with patients, doctors, regulators and industry members about their needs and challenges and are well placed to provide input to this inquiry. We welcome the opportunity to provide insights on the current barriers to patient access in Australia and what might be done to address them.

2.0 Executive Summary

We recommend that the following actions be considered:

a) Australia has done a number of things well, including establishing high quality standards for products, making products prescription only, creating a national framework for approvals and providing a supportive R&D framework, and these should be continued
b) We believe that the patient numbers and growth rates over the past 12 months suggest that, in most jurisdictions, access approvals are no longer a significant barrier and the current access model including **high quality specialised clinics should be encouraged**
c) Despite access approvals becoming easier, broad GP participation remains a challenge and doctors generally **lack knowledge and understanding of cannabis-based medicines** and the effort involved in the approval process
d) Cost is a major challenge for patients due to lack of PBS subsidy. Current mechanisms for offsetting costs for particular groups in need should be encouraged, for example, via the Department of Veterans Affairs, Medicare and WorkCover
e) The **economic case for broader subsidies using PBS or Medicare should be evaluated**

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f) Driving laws need to change to allow patients with THC in their system from past use, and whom are not impaired, to avoid penalisation. Australia has the opportunity to undertake **world first research** to establish a framework and technologies to support driving and medicinal cannabis treatment
g) Australian cultivators and manufacturers are required to manufacture to PIC/S GMP standards but currently these standards are not being applied to foreign imports. Now that locally available product has entered the market we recommend that by the end of Q2 2020 the **ODC / TGA should start enforcing GMP standards** on product imports

3.0 Four barriers to patient access

While there are many barriers to patient access in Australia, we suggest they all generally fall into one of four categories. For each category we have indicated the relevant term of reference. These are:

1. State/Territory restrictions (a; c; j)
2. Finding a suitable doctor (a; c; e; f; g; j; k; l)
3. Cost (b; i; j; l)
4. Driving (j; k)

4.0 State/Territory restrictions

The Federal government should be commended for the creation of the online Special Access Scheme portal which has effectively streamlined much of the paperwork required to submit and receive approval for requests for Special Access to unregistered medicines including cannabis. It is fair to say that the Federal government's patient access pathways are no longer a significant barrier to patient access.

Doctors and patients still face a confusing and fragmented set of requirements and restrictions at the State/Territory level. FreshLeaf recommends that doctors specialising in General Practice should be able to use medical cannabis to treat patients directly under their care without being required to have additional State/Territory or condition specialist approval/support. This is currently the case (in most situations) in QLD, NSW, VIC and the NT. More work needs to be done to coordinate a reasonable and harmonised set of patient access regulations across the remaining jurisdictions. For reference, here is a summary of the State/Territory requirements as summarised by Little Green Pharma as of 12/11/2019:

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https://www.littlegreenpharma.com/healthcare-professional-focused/state-by-state-breakdown

Quick Guide Medical Practitioner (GP)

Prescriber authority & documents needed to lodge SAS-B application:

		WA	VIC	NSW	QLD	TAS	NT	ACT	SA
Authorised	Medical Practitioner (GP)	YES*	YES	YES	YES	NO	YES	YES *with letter of support*	YES
DOCUMENTS REQUIRED	TGA online application			YES		–	YES		YES
	State Health online application	YES *Done simultaneously via TGA portal*	YES *Done simultaneously via TGA portal*	NO *Unless under the age of 16 or in drug treatment program*	YES *Done simultaneously via TGA portal*	–	NO *However, a 'notification' to NT Chief Health Officer is required if the patient is on S8 for 2+ months*	YES *Done simultaneously via TGA portal*	NO *the patient can be put on a 60-day trial prior to seeking state health approval, IF they are not on any other S8 medications*
	Clinical Justification and Treatment Plan	YES	YES	YES	YES	–	YES	YES	YES
	Cannabis-based consent form	YES	NO**	NO**	NO**	–	NO**	YES	YES
	Letter of support from Specialist	YES	NO *(unless a GP is applying for a condition outside their normal area of expertise)*	NO	NO	–	NO	YES	NO

* GPs in WA will still be required to seek specialist approval when prescribing for children under the age of 16 and for patients who are drug dependent or have a history of drug use.
**Cannabis-based consent form is not required but is recommended to have on file for the patient in any case.
Updated 12th November 2019

little green pharma

Of particular concern is the state of Tasmania. Although the Controlled Access Scheme in that State subsidises the costs of medicines prescribed to approved patients, the restrictions placed on who can prescribe and who can access medical cannabis are not in-line with national best practice.

FreshLeaf recommends that the Commonwealth, through COAG, reinvigorate the harmonisation project initiated in early 2018 to achieve proper, consistent regulation across the States and Territories.

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6.0 Finding a suitable doctor

When patients want to consider medical cannabis as a treatment option, the first challenge they face is finding a suitable doctor. Most patients would prefer to see their regular doctor, but often doctors are not trained in how to use medical cannabis products in clinical practice, or are unaware of the approval pathways, or both. Often a patient's regular doctor will be unopposed to or supportive of trialling medical cannabis but choose not to pursue a prescription themselves. This puts the onus on the patient to find a doctor who is interested, educated and motivated enough to trial cannabis medicines.

6.1 Clinics

A popular way to find an appropriately trained doctor is to engage with one of the many patient access facilitation and clinic companies. If a patient's regular doctor is not appropriately trained, finding a clinic is the next logical step for many. However, with the recent clarification of the TGA's advertising guidelines, this will become difficult if not impossible. Companies that specialise in the use of medical cannabis are prohibited from having the word 'cannabis' on their website. In fact, clinics have been advised that even referencing the endocannabinoid system - a naturally occurring endogenous part of human physiology - is not permitted.

FreshLeaf recommends that, similar to the regulated cosmetics industry, medical cannabis clinics should be able to inform the public of their services so long as no specific brands or active ingredients are mentioned.

7.0 Cost

Medical cannabis is expensive. If a patient's regular GP is prevented from prescribing due to State/Territory laws, or if they are not trained in cannabis therapy and the access pathways, patients need to be referred to a specialist or a cannabis clinic. Seeing a specialist is expensive and seeing a clinic is usually not bulk-billed. The paperwork involved in submitting an application on behalf of a patient has been reduced with the TGA online portal but is still required. This imposes am additional time cost on doctors that they need to recoup through fees, further increasing costs.

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7.1 Product costs

Products are also expensive. According to FreshLeaf Analytics' research, Australian patients are paying on average $5-15 per day for their medication. Paediatric epilepsy patients continue to be hardest hit by product costs and are paying on average >$50 per day for their medication. There are two main factors contributing to high product costs: the lack of government subsidies and the lack of large-scale domestic product suppliers.

FreshLeaf recommends that the Commonwealth develop an industry development plan to facilitate the speedy development of low-cost, locally produced medicines.

7.2 The PBS

The Pharmaceutical Benefits Advisory Council will only consider ARTG-registered medicines for subsidy. The only ARTG-registered cannabis medicine, nabiximols, has previously been considered and rejected by the PBAC as not being cost effective enough. Clearly the PBS is unsuited to subsidising cannabis medicines which are almost universally unregistered and unpatented. There is little commercial incentive for any company to invest in the kinds of clinical trials required for PBS subsidies as their products are botanically derived generics and not protected by patent monopoly rights.

FreshLeaf recommends that the economic case for broader subsidies using PBS or Medicare should be evaluated through a Commonwealth-lead health economics study.

7.3 Industry regulation

It is FreshLeaf's assessment that the primary way to reduce product costs is by having large-scale domestic cultivation and manufacture. Product costs are therefore directly linked to Australia's medical cannabis industry regulation. The Narcotic Drugs Act and the Office of Drug Control have recently been the subject of an independent review by John McMillan AO. The first step towards reducing product costs should be the speedy implementation of the findings of this review.

The implementation of these recommendations should be assessed by how many Australian companies bring low-cost, locally cultivated products to market. If product costs remain high even after sufficient production is achieved, industry regulation must be improved until such time as medicines become affordable.

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FreshLeaf notes that since November 2016, when the medical cannabis scheme was implemented, two companies have managed to bring Australian-cultivated products to market. We anticipate several more locally cultivated products to become available in early 2020.

FreshLeaf recommends that, once sufficient domestic production has been achieved, product quality standards should be harmonised and imported products should be required to adhere to PIC/S GMP manufacturing standards. We anticipate this will become appropriate within the next six months.

8.0 Driving

In every State and Territory it is an offence to drive while having a detectable level of THC in one's body. This means any patient who is prescribed a Schedule 8 medical cannabis product must cease driving for the duration of their treatment or face the risk of serious drug driving offences.

People should not drive while they are impaired. But most medical patients never experience impairment and those that do are able to manage their impairment as they would with any other sedating medication. Benzodiazepines, for example, have been shown to impair driving ability. And patients prescribed those drugs are advised not to drive if they feel impaired. Patients prescribed benzodiazepines are not forced to choose between treating their medical condition and retaining their personal autonomy.

This restriction means many patients who are recommended medical cannabis by their doctor choose not to commence with treatment. And many patients request to only be prescribed a Schedule 4 cannabis medicine, which may not be effective, or as effective, for their indication. This reduces the quality of medical care they are able to receive.

There may come a time when a viable, accurate and cost effective technology exists to detect THC impairment. And Australia is well placed to lead the scientific research programs required to deliver such an outcome. But until that happens, this issue must be addressed through policy.

FreshLeaf recommends retaining the existing random roadside drug testing regime as is, but legislate an exemption for patients not accused of dangerous driving who can produce a current and valid prescription.

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9.0 Conclusion

In conclusion, FreshLeaf recommends that:

- The Commonwealth re-commit itself to harmonising State/Territory access pathways
- Advertising regulations be clarified to permit specialist cannabis clinics to inform the public of their medical services
- The economic case for PBS, MBS and other subsidies be investigated by the Commonwealth
- The recommendations from the McMillan Review be quickly implemented
- Driving laws be amended to reflect the legality of medical cannabis and to protect medical cannabis patients from unnecessary legal risk

FreshLeaf Analytics welcomes the opportunity to contribute to this inquiry and is happy to provide additional information and commentary as required.