20 December 2019

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

To the Committee Secretary,

The LeafCann Group is pleased to provide a submission to the ***Current barriers to patient access to medicinal cannabis in Australia*** inquiry. LeafCann is a fully licensed medicinal cannabis company dedicated to providing high quality medicine to Australian patients.

LeafCann is a founding member of Medicinal Cannabis Industry Australia (MCIA) and has contributed to MCIA's submission. Our response to the Terms of Reference below should be read in addition to the MCIA submission.

LeafCann response to the Terms of Reference

(a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials;

The effectiveness of the SAS is limited by the health professionals prepared to prescribe medicinal cannabis and negotiate the online application process. At present there are still many doctors who aren't confident to use the portal for prescribing and therefore less patients are going through the SAS than what could potentially be the case. Tasmania should be given any support it needs to adopt the online portal.

The differences between states and territories in their requirements for SAS applications needs to be addressed; only one approval, from the TGA, should be needed. This should apply to any GP and

not limited to specialists, as is the case in some states. There should also be scope in the future to allow Nurse Practitioners to use the SAS online portal in some circumstances, particularly in remote areas where GPs rarely see patients.

The barriers to accessing products containing only Cannabidiol (CBD) could be removed by down-scheduling these products from Schedule 4 to Schedule 3, which would allow for doctor recommendation without a script, but dispensed only at a pharmacy by a qualified pharmacist. This would allow for faster access without having to get a script approved through SAS every time a patient wants to renew a prescription. Given the safety profile of CBD these products can be dispensed with confidence under the supervision of a pharmacist. There is also an opportunity to create a separate category for Cannabinoid medicines (see our response to (b) below)

(b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;

Subsidising patient access through the PBS is traditionally only available to products that have been patented and registered with the TGA after years of clinical trials. The evidence base is building for medicinal cannabis; however, clinical trials do take time. What is important is that where a medicinal cannabis product has, or is, being tested and shows positive results with a history of safe use, the opportunity is there to provide relief to patients under the guidance of a health professional.

The biggest problem towards registration of medicinal cannabis products lies in the fact that they are more difficult to patent. This needs to be addressed by the TGA with a view to determining how medicinal cannabis products can be registered without a patent. One option is to develop a category for medicinal cannabis in which the burden of clinic trials is not as onerous, given the safe history of use. The industry is prepared to work with the TGA towards a solution for ensuring safe, effective medicines can be registered while at the same time ensuring sub-par products do not enter the system.

One solution is to create a separate category for Cannabinoid medicines through the TGA. This would be parallel to the “TGA Listed Assessed” (AUSTLA) category which is intermediate between TGA Listed (AUSTL) and TGA Registered (AUSTR) and would require a dossier of data that supports efficacy for particular indications, but not the same level of safety data as required for AUSTR, because of the inherent safety profile of cannabinoids. LeafCann suggests the category of “AUSTC” to indicate cannabinoid medicines.

Only after the registration hurdle is overcome can the issue of subsidies through the PBS be addressed. Cheaper medicine makes medicinal cannabis more accessible, though it should not come at the expense of quality. Only products meeting the highest of standards should enter the Australian market – whether domestically or internationally produced. The industry has confidence in the TGA to be able to assist in the registration of medicinal cannabis medicines.

Furthermore, if Australia is to become a world leader, the development of high-quality medicinal cannabis products is essential. Registration of products through the TGA is key to developing an international reputation of high standards and providing consumers overseas the confidence to source Australian products.

(c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;

The best option for an effective and consistent medicinal cannabis scheme is to have one scheme adopted by all states with no variations. If this was unified at the national level it would be much easier for the Department of Health to administer and would reduce confusion among patients and health professionals. It would also make it easier for those medicinal cannabis manufacturers working in more than one state to avoid multiple frameworks.

Having only one system provides clarity and assurance to the medicinal cannabis industry.

(d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;

The Australian regulatory system has shown that government departments are not resourced well enough to provide the services with which they are tasked. For instance, the ODC has been given a variety of functions, yet it has become bogged down in assessing applications for medicinal cannabis licences and a variety of permits. The ODC is better off to only take on the task of assessing applications. This could be done in its current environment or as a unit within the TGA, which has a larger resource and knowledge base which it can use more effectively.

The TGA is better suited to taking on tasks such as assessing permits, and variations to permits, particularly where these permits relate to importing of products that will be used for manufacturing or direct supply to patients. What is most important is that all areas in government dealing with regulatory issues be empowered to make decisions based on the evidence in front of them in a timely manner. Current anecdotal evidence from licensed companies has shown waiting periods

well in excess of 6 months for a simple variation to a permit. Some cases have had companies submitting an identical permit that was previously approved and still having to wait for several months. This cannot continue if the industry is to progress at the speed needed to be competitive.

(e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;

Many current health professionals have been educated and trained in a system without any focus on medicinal cannabis, or indeed the fundamental underlying system of endocannabinoid receptors and their endogenous ligands. This transfers directly to the ability of health professionals to negotiate the TGA framework for prescribing cannabis.

Unlike traditional pharmaceutical practice whereby health professionals might be trained on a drug-by-drug basis, the medicinal cannabis industry needs to support a broader based approach because the endocannabinoid system, and its integrative role in health, is new to many health professionals. Without a detailed understanding of the endocannabinoid system these health professionals do not have the framework understanding in which to place cannabinoid product-specific information.

The key is for health professionals to attend Continuous Professional Development (CPD) courses conducted by non-industry aligned organisations, such as the Australasian College of Nutritional and Environmental Medicine (ACNEM), for example. Upskilling health professionals with fundamental system-level information is crucial to ensuring more of them are able to prescribe medicinal cannabis.

(f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;

The history of safe use and the increasing evidence base means it is time to include the endocannabinoid system into undergraduate courses for health professionals. Current doctors without training should also be able to sign on to Continuous Professional Development (CPD) courses and receive the training they need to give them confidence in prescribing medicinal cannabis. Medicinal cannabis has been accepted as an appropriate treatment for several conditions internationally.

As stated above in (e), current exemplar courses to look at are those conducted by the Australasian College of Nutritional and Environmental Medicine (ACNEM). Courses such as these should be available in every state and territory and available to all health practitioners.

(g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;

There are a few non-industry aligned organisations currently operating high-quality CPD courses and provide useful information for doctors in Australia. More high-quality entrants to this field will provide greater opportunities for health professionals to obtain the necessary skills and understanding to prescribe medicinal cannabis. Additionally, Universities have an opportunity to develop specialised postgraduate courses in medicinal cannabis and should be encouraged to do so.

Australia's research capabilities are strong and amongst the best in the world. Providing more incentives to universities and research organisations will facilitate further developments and innovation in what is still a new field. Research projects could include new cannabinoid products, novel methods of dose administration and concepts such as microdosing.

(h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;

There are many producers ready to enter the market but cannot pass the licensing stage in a timely manner. This runs the risk of fewer operators and therefore higher prices. Furthermore, some industry operators are currently waiting over 6 months for approvals to minor variations in permits that were previously approved. The situation is forcing legitimate operators to reassess their business models in Australia and could lead to some exiting the industry altogether because of the massive bottleneck in what should be simple approvals.

It cannot be emphasised enough that delays in patient access to medicinal cannabis can be fixed further up the supply chain by addressing the current assessment processes at the ODC. Decisions must be made on either providing significantly more resources to the ODC or moving some its functions to the TGA.

(i) the current status of the domestic regulated medicinal cannabis industry;

As has been stated earlier, there is a massive problem in the assessment of applications for licences and permits. The current delays have meant that the domestic industry is moving at such a slow pace that very few players are currently manufacturing finished product from domestic supply. In some cases operators are not even able to store their products in a vault because of regulatory hurdles.

Improved licensing and regulation will allow more domestic production and therefore lower prices, making medicinal cannabis more affordable to patients.

(j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;

The struggles of patients, and relatives of patients, to access medicinal cannabis has been well documented in the media. Although the situation is gradually improving there is still a lot of angst in the community because although medicinal cannabis is legal, it is still unobtainable in a timely manner for many patients and too expensive to purchase through legal sources for others.

The regulatory regime in Australia needs to allow for faster approvals and less stringent requirements for access, particularly given the safety profile of cannabinoids. Where a patient has examined traditional options without success, they should be able to work together with their doctor towards trialing medicinal cannabis. Forcing patients to continue other medication or treatments until all avenues have been exhausted impacts on the mental health of these patients who continue to suffer, particularly those with chronic pain.

On top of the mental stress experienced by those struggling to access legal medicinal cannabis is the complication for those who resort to growing their own cannabis or resorting to the black-market and thereby open themselves to criminal charges. Parents who place the health and welfare of their children before all else are susceptible to going down this path and face the daily stress of being caught for supplying a drug they can't access legally for their child.

(k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;

The tyranny of distance is well known as a barrier for health services in remote areas that many of us take for granted in urban areas. General practitioners are not able to regularly visit some rural and remote areas and those in remote areas struggle to afford the costs associated with travel to cities for health services.

The nurse practitioner model allows nurse practitioners to prescribe certain medications, sometimes in consultation with a health professional by phone. This model could work effectively with medicinal cannabis where other avenues have been exhausted and there is no risk to the patient. A nurse practitioner is "a Registered Nurse experienced in their clinical specialty, educated at Masters Level, and who is endorsed by the Nurses and Midwives Board of Australia (NMBA) to provide patient care in an advanced and extended clinical role." This model should be looked at as a possible mechanism to deliver medicinal cannabis to those in rural and remote areas for certain conditions as it would be one way to remove barriers to access.

(l) the significant financial barriers to accessing medicinal cannabis treatment;

The lack of domestic production has meant that prices have not come down since legalisation. Anecdotal evidence suggests that patients pay between $200 - $600 per month in Australia. This precludes many from using legally produced products and can lead to some being tempted to source illicit cannabis from family, friends or other black-market suppliers.

Regardless of their claims, black-market producers do not have the same level of control and product quality that is assured by a licensed producer. Even small variations in growing conditions can affect the composition of a plant and therefore provide different reactions in the user. This could lead to dangerous situations in which someone using cannabis from a non-licensed source is unable to drive, operate machinery, or stay awake at work.

Improving the cost for medicinal cannabis is most effectively done by facilitating an industry that can produce high-quality products without excessive regulatory burdens. Removing regulatory obstacles will lead to more product being available at a more affordable price.

(m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that

Media reports suggest at least 150,000 people are accessing illicit cannabis to treat their ailments, although this could be much higher. What is even more concerning than the large number of patients going to the black market is that all of them are placing themselves at risk by doing so. They risk their health by using products that are of questionable quality and unknown composition, regardless of the claims of the supplier. These patients also risk their livelihoods if caught, with many people complacently believing they won't receive criminal charges.

Not only must access barriers be removed, but more must be done to educate the public about the dangers of accessing medicinal cannabis from non-licensed sources.

(n) any related matters.

The issue of driving a vehicle remains a common question from those looking to use medicinal cannabis. Current drug testing only tests for the presence of drugs such as cannabis, however, this does not necessarily mean that they are impaired to drive. Roadside drug testing should be about impairment and not a positive reading on a detection device. This is an important matter that is impacting on some patients' decision to use medicinal cannabis and must be addressed if patients are to take medicinal cannabis with confidence in the future.

As detection devices become more sensitive, it is now possible to have not taken any medicinal cannabis for a month and still have a positive reading. The Department of Health must work with the judicial system, particular police departments, to establish protocols for testing a driver that can demonstrate they are a medicinal cannabis patient and are not impaired to drive.

Sincerely,

Elisabetta Faenza

CEO LeafCann Group