Medicinal Cannabis Industry Australia (MCIA)

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

December 2019

1.0 About Medicinal Cannabis Industry Australia (MCIA)

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make this submission to this Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia.

MCIA is the peak industry organisation for Australia's licensed 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 is providing stewardship for an economically sustainable and socially responsible industry that is trusted and valued by patients, the medical community and governments. The Australian industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products.

2.0 Introduction

The Senate Community Affairs References Committee is conducting this inquiry into the current barriers to patient access to medicinal cannabis in Australia to look at the:

- appropriateness of the current regulatory regime
- suitability of the Pharmaceutical Benefits Scheme for subsidising access to products
- training and education of doctors in relation to treatments.

The Inquiry is also interested in comparison of Australia's regulatory approach to other countries and implications for patient access.

3.0 Background

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 streamlining to ensure it is meeting the objectives of the Act and operating efficiently and effectively. MCIA welcomes the support of the Government in adopting all recommendations from the McMillan Report as a positive step in improving the current arrangements. However, MCIA also recognises and has promoted the need for further improvements to enable licence holders to operate and to facilitate patient access to timely, cost effective and quality Australian product.

MCIA believes a strength of the Australian approach is 'Australian quality' product underpinned by GMP standards and relevant Therapeutic Goods Orders (TGO). The values of Australian quality, namely plant derived, regulated and true to label will deliver confidence to patients and the healthcare.

In order to capture these benefits, the existing system must be to streamlined and improved to enable Australian produced product to be available to Australian patients. This will help alleviate pressures on patients through improved quality and consistency of products and affordability.

There are a number of barriers to patient access, but MCIA believes that these barriers can be addressed within the existing system, in particular, through prioritisation of licence holders through the Office of Drug Control (ODC) system.

Investment in education and information is essential to build confidence amongst patients, doctors and the broader healthcare sector.

4.0 Key areas to address current barriers to patient access

4.1 Effectiveness of the regulatory framework

As noted above, MCIA is supportive of a framework that enables the development of a medicinal cannabis industry in Australia and the access for patients to a quality controlled, true to label, compliant product that that is already demonstrating the potential to positively contribute to a broad range of conditions.

While the number of patients seeking access has grown rapidly, this is significantly less that the number of patients that could legitimately access medicinal cannabis if approval processes were improved. Improving and streamlining the existing legislation and operations of Office of Drug Control will assist to facilitate patient access to timely, cost effective and quality Australian product. To enable a domestic supply which has the rigors of the Australian regulatory framework applied, there is an urgent need to ensure that licence holders have an efficient and timely pathway through ODC which is not hindered by unnecessary regulatory process or restrictions, to enable licence holders to obtain the relevant permits and other regulatory approvals required to support operations and facilitate the supply of Australian product to the market.

Some of the unnecessary regulatory process or restrictions include:

- Regulatory authorisations are involved at multiple steps
- Turnaround times are drawn out and variable, even for repeat activity by the same applicant
- Pipeline management that is making the ability to be responsive to the body of Australian patients extremely difficult. For example, out-of-stock issues result due to hold ups in permits and slow approval processes necessitate the doctor applying for new approvals for a different formulation/supplier or treatment delays for the patient. Impost of regulations on pipeline management mean a patient may be subject to switching medications or coming off/on an effective medicine because of stock issues

MCIA believes that the regulation of medicinal cannabis under a dual ODC/TGA framework assists to provide confidence to doctors and the healthcare sector along with acceptance of medicinal cannabis as a 'medicine'. *Thus, MCIA supports improving the current system rather than introducing a new regulatory framework.* Further, the MCIA believes that the existing system is the most suitable structure to deliver the best outcome in terms of delivering patient access to trusted and quality products in a timely and effective manner.

A clear objective of the legislation is to enable patient access to medicinal cannabis legitimately and with confidence that it meets the required quality framework. One factor that will assist to facilitate this is access to affordable local products for patients. This will be achieved if the license holders can achieve scale and operate in an efficient market and appropriately balanced regulatory environment.

4.2 Current status of the domestic regulated medicinal cannabis industry

Licence holders, and potential licence holders, have encountered a considerable number of delays in the progressing of licences, permits and variations. These delays have had a significant impact on Australian patients, the Australian medicinal cannabis industry, and individual businesses.

The MCIA submission to the Narcotic Drugs Act review identified a range of issues regarding ODC operational activities including lack of transparency around status of applications/variations, significant delays with license and permit assessments, various inefficiencies (including duplications) in the submission and review process, and the lack of a triaging approach to applications. While MCIA recognises that the under-resourcing of ODC has contributed to this, processes and interpretations are also key factors hindering innovation and development. Further issues are caused by the ODC continuing to be faced with new applicants seeking to enter the industry, while not being able to adequately service existing licence holders.

MCIA welcomes the implementation of the McMillan Report recommendations, which aim to address some of these inefficiencies, but there is opportunity for further improvement of the system. In particular, there is an urgent need for a risk-based approach to exercising regulatory functions. Significant delays have been experienced across licence, permit and variation applications e.g. our members have experienced typical processing times of around 6-12 months, but as high as 24 months with some still in the system that may exceed this. A number of operational factors are impacting this including the process for managing applications, lack of transparency, inadequate pathways for resolving queries, unnecessary delays, etc.

The impact of these inefficiencies and delays include:

- Reduced patient access and increased cost of access
- Increased costs to business which will further impact patients
- High level of business uncertainty with consequential impacts on product supply, employment and growth
- Lack of confidence by Patient and Health Care Professional in respect of the ongoing availability of Australian produced products, as compared to imported products

4.3 Patient access pathways and barriers

There are several barriers or factors limiting patient access including patient affordability, regulatory impacts, reluctance by GPs to prescribe, the focus on medicinal cannabis as treatment of last resort and supply issues.

These barriers/factors impacting patient access could be reduced or assisted through:

i) Facilitating access to Australian product through streamlining and operationalising the regulatory system. This could be achieved through:
   - Addressing the ODC operational issues outlined above
   - Repositioning the assessment of risk of diversion – currently the consideration of risk of diversion in isolation and at times inconsistent with and in excess of existing measures associated with other Schedule 4/8/9 substances, has resulted in over complication of the supply pathways, with potential for discouraging participation and reducing supply for Australian patients
   - Addressing inconsistencies by regulators in regard to statutory interpretations
   - Engaging the COAG Council of State health ministers to remove the last State-based replications of TGA approval processes and remove all medicinal cannabis specific processes. The unregistered medicine aspect is under the remit of the TGA, and existing processes around prescription and narcotic management at the State level are well established

ii) Building confidence through supporting evidence and transparency i.e. facilitation of research and trials to provide patients and medical practitioners with better information around the products, target conditions, dosages, etc. Three approaches that would help facilitate research and trials are:
   - through simplification of research licences for credible parties such as universities where they already have the approved status and experience in handling schedule 9 drugs and thus, understand issues such as diversion;
   - making licence/permit applications less prescriptive in relation to end products while maintaining reporting requirements and compliance. Currently, product development activity under the cannabis research cultivation licence and permit (regulated by the ODC) is fundamentally different to the way medical research or product development (under TGA regulation) is undertaken; and
   - providing an alternative and simplified clinical trial process such as the N=1 protocol.

iii) Improving affordability and specifically whether medicinal cannabis should be covered by the PBS. There is general recognition of the need for a compassionate pricing system and MCIA suggests that consideration be given to alternative models to the PBS that provide for pricing relief for patients as medicinal cannabis does not precisely fit into the PBS guidelines. Alternative models or options could include approaches such as registration, amended PBS guidelines to include medicines that are TGO93 compliant, or develop an alternative model. There are potentially benefits to the health system from expanded use of medicinal cannabis if it enables the reduced use of other medicines and thus, this could help offset any compassionate pricing system for medicinal cannabis.

MCIA also suggests that providing a dedicated item code in the Medicare Benefits Schedule (MBS) would assist doctors prescribing medicinal cannabis.

MCIA also encourages the Senate Committee to look at the potential for medicinal cannabis to be subsidised under health insurance schemes. Again, there could be offsetting factors if medicinal cannabis reduces use other medications and/or other costs with chronic conditions.

iv) Supporting and funding healthcare practitioner education (doctors, nurse practitioners, pharmacists and others). This is critical to promote change in attitudes to medicinal cannabis. MCIA supports the inclusion of the endocannabinoid system in education/training programs for the healthcare sector. We also note that the New Zealand Ministry of Health is seeking $650,000 of Government funding to set up a prescriber education program and MCIA would encourage consideration of a similar approach for Australia

v) Removing the requirement for medicinal cannabis to be 'the last possible option' i.e. a doctor should not have to exhaust all options before medicinal cannabis can be considered a possible medicine

In New Zealand, the Government undertook consultation that suggested making it easier for doctors to prescribe medicinal cannabis by not requiring Ministry of Health approval. This approach has been adopted and The Ministry of Health has recommended that all doctors be allowed to prescribe CBD and THC products. General practitioners will be able to prescribe products with known levels of tetrahydrocannabinol (THC) and cannabidiol (CBD), within a quality standard. While recognising that Australia has some complexities with State based legislation and approaches, a GP based prescription approach could benefit Australian patients.

vi) Clarification of issues such as driving regulations and medicinal cannabis use

Given the delays in operationalising medicinal cannabis licence holders who can produce Australian product, the sector today is reliant on imported products. This pathway is important to enable patients to access the medicine and to help develop pathways and build information and awareness of medicinal cannabis. However, this does come at a higher cost for patients and an increased risk of delay and/or shortage of continual supply, thus the emphasis should be on developing and delivering Australian product. It is also critical that imported products are required to meet the same standards as locally produced products to ensure a level playing field and to provide patients with assurances regarding product quality and that the TGA/ODC actively monitors and takes appropriate action against Sponsors who import and/or supply products which do not satisfy Australian regulatory requirements.

A strong domestic supply will remove the impact of a lack of commitment from, and changing priorities of, international suppliers who supply into Australia.

5. Summary

MCIA appreciates the opportunity to provide this submission to the Senate Review and would be happy to provide any additional information that the Committee may require.

MCIA acknowledges that there are a number of barriers to patient access today, but believes that there are solutions that can be put in place to address these and ensure that those that need this medicine are able to access it in a timely and affordable manner.