Australasian College of Nutritional and Environmental Medicine Inc

Transforming Global Health

Submission:
Senate Community Affairs References Committee inquiry into the current barriers to patient access to medicinal cannabis in Australia

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On 14 November 2019, the Senate referred an inquiry into the '***current barriers to patient access to medicinal cannabis in Australia***' to the Senate Community Affairs References Committee for inquiry and report by 26 February 2020. Submissions are requested by 17 January 2020.

Terms of Reference for Inquiry

The current barriers to patient access to medicinal cannabis in Australia, including:

a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials;
b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;
c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;
d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;
e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;
f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;
g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;
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;
i) the current status of the domestic regulated medicinal cannabis industry;
j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;
k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;
l) the significant financial barriers to accessing medicinal cannabis treatment;
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; and
n) any related matters.

This submission outlines the response of **Australasian College of Nutritional and Environmental Medicine (ACNEM)** to the Terms of Reference listed for this Senate Inquiry into

the '*current barriers to patient access to medicinal cannabis in Australia*'. It draws on first-hand knowledge and experience of ACNEM members who prescribe medicinal cannabis and/or work within the Medicinal Cannabis (MC) industry.

(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 Special Access Scheme (SAS) and Authorised Prescriber (AP) Schemes have served an initial purpose at a time when medicinal cannabis (MC) access was first introduced in Australia (in 2016), ensuring that medical practitioners can therapeutically justify the prescribing of MC for certain clinical indications, and that they have sufficient knowledge to prescribe it.

The SAS and AP Schemes are triggered because MC is considered an 'unapproved good' by the Therapeutic Goods Administration (TGA). MC has been able to be prescribed legally by medical practitioners since 2016. We are now five years down the track (2020). The question now is, why is MC still 'unapproved'?

The TGA website states: *"At present, scientific evidence for the use of CBD and THC in most conditions is limited, and does not support medicinal cannabis as a standalone treatment"* [1]. This is not true. The evidence base for the efficacy of MC is considerable for several different conditions including chronic pain, chemotherapy induced nausea and vomiting (CINV), spasticity associated with multiple sclerosis (MS), sleep disorders, epilepsy, inflammatory conditions, mental health conditions including anxiety and PTSD, to name a few. The National Academies of Science, Engineering and Medicine's 2017 report on MC, which summarised scientific evidence from systematic reviews and randomised controlled trials, noted that there is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults, CINV and spasticity associated with MS, and a moderate level of evidence for efficacy in treatment of short-term sleep disturbance associated with a range of conditions [2]. The evidence base has grown substantially since that report was published in 2017. An argument by some within the industry is that more research is needed in Australia. However, it is argued that it is neither reasonable nor logical that clinical research must be conducted in Australia in order to prove MC is efficacious for particular conditions, when well-conducted research has already been conducted in other countries.

The SAS and AP scheme are time-consuming, and we believe, unnecessary and serve to put doctors off prescribing MC. The AP Scheme allows doctors to apply to prescribe specific MC products for specific clinical conditions. The application process for approval is lengthy and requires doctors to be first approved by a human research ethics committee (HREC) or a specialist college (we know of no specialist colleges processing AP applications). The National Institute of Integrative Medicine (NIIM) HREC is the only HREC which has developed a specific process for approval of AP applications, with the TGA giving the final approval. Once approved, the doctor then does not have to apply for permission from the TGA to prescribe for those particular conditions she/he is approved for, however if they decide they want to prescribe a different MC product, they must go through the AP approval process again. This entails re-

applying to the HREC or specialist college for approval, and then again to the TGA for final approval. Likewise, if the doctor wants to prescribe it for a different condition, she/he must either reapply to the HREC or specialist college then to the TGA to be approved to prescribe for that additional condition (or just use the SAS instead). Under the AP Scheme, doctors still need to apply to their state/territory health department to prescribe MC products which are S8 medicines (typically those containing THC). As part of the AP approval conditions, doctors must submit 6 monthly reports to the HREC and TGA. AP approval must be updated yearly.

Whilst the SAS process is faster, doctors still have to complete an online submission justifying why they are prescribing MC for that condition. This is time-consuming, and some doctors are passing the cost of this onto their patients. This online form simultaneously is sent to the state/territory health department as permission is needed from them to prescribe MC products (since drugs and poisons legislation is state/territory-based).

Another issue is that in some states, specialist approval is required for a GP to prescribe MC. Often the specialist is not educated about MC and may not be in the best position to make a decision on whether it may help the patient or not. There are no other drugs in Australia for which a GP must seek permission or a letter of approval from a specialist in order to prescribe. We believe that this is unnecessary. GPs are specialists in their own right.

New drugs enter the marketplace all the time. Doctors are not required to justify their choice of drugs in the way that they are if prescribing MC. The TGA's SAS and AP Schemes require that doctors have tried other approved medicines and that MC should only be used as a last resort. The TGA website states that 'As noted by the Queensland Government's *Clinical Guidance for the Use of Medicinal Cannabis Products*[1], ***medicinal cannabis is not considered a first-line therapy for any indication'*** **[3]**. Such a statement is an example of regulatory over-reach. It is up to the patient and doctor to decide what therapy is most appropriate. It is also in contravention of a patient's right to choose what they are treated with (in consultation with a healthcare professional), and patients may want to use MC as a first option, not the last resort.

We believe that it is now time for the TGA to change the status of MC from an 'unapproved good' to an 'approved good'. This will then do away with the requirement that medical practitioners must use the SAS or AP schemes. Medical practitioners should be able to simply prescribe MC like any other medication.

In addition, currently cannabidiol (CBD) products and products containing tetrahydrocannabinol (THC, the only constituent of Cannabis sativa that is potentially intoxicating) are on Schedule 4 (S4, Prescription Only medicine) and Schedule 8 (S8, Controlled Drug) respectively of the Standard for the Uniform Prescribing of Medicines and Poisons (SUSMP) [4]. An exception is that if a CBD product contains > 2% of other cannabinoids, it is also considered an S8 drug [4]. It is argued that CBD is sufficiently safe to be regulated as a listed or assessed-listed or registered medicine on the Australian Register of Therapeutic Goods (ARTG) as other herbal medicines are.

Regulating CBD in the same way as any other herbal medicine in Australia (on ARTG) would serve to greatly increase patient access to CBD and would allow other suitably qualified healthcare practitioners (e.g. registered Chinese medicine practitioners, qualified western herbalists) to prescribe it in addition to western doctors. This is likely to significantly increase the number of healthcare practitioners willing to prescribe MC.

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

Subsidisation of MC products under the Pharmaceutical Benefits Scheme (PBS) would have tremendous benefits for the Australian public, helping make MC more affordable.

It is known, anecdotally, that patients are turning away from prescribed MC products to the 'grey market' due to the lack of affordability of products in Australia. This obviously puts patients at risk as the quality of such products is unknown. Australian MC products are very costly in comparison with similar products in Europe, the US and Canada. For example, it is possible to buy a 30ml bottle of CBD oil in Europe for around 30 Euros. In contrast, a bottle of CBD oil in Australia can be between $150 and $300. Some patients, for example those with epilepsy or cancer may require several bottles of MC per month as their daily dosage is higher than average. This becomes unaffordable for most Australians. The high costs to MC companies importing MC products from overseas, detailed later, is a major reason for the high cost of MC products in Australia current.

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

There is overlap in several areas of the regulation of cannabis, in particular from the commercial side. For example, to import medicinal cannabis, an import licence is required from the state/territory *and* federal levels. Why this is so is not clear and is an example of duplication which could be reduced.

It would make sense for the responsibility for issuing MC import licences to be devolved to the states and territories. Duplication creates time delays and costs companies money. Costs then are passed on to the end user, the consumer.

From the prescriber perspective, since drugs and poisons legislation are state/territory based, in general permission must be sought for medical practitioners to prescribe S8 MC products from the state/territory health department (under both the SAS and AP Scheme). There are exceptions to this, however. For example in Queensland, doctors holding a specialist qualification (including specialist general practitioners) are exempted from applying to their state health department to prescribe a S8 MC product unless the patient is drug-dependent https://www.health.qld.gov.au/public-health/topics/medicinal-cannabis/clinicians/prescribing.

In NSW, it is not a requirement any more to apply to the NSW health department to prescribe S8 MC products unless prescribing or supplying to a drug dependent person, or a child (under 16 years) or for a clinical trial. However the doctor is expected to be a specialist in the management of patients with the disease being treated with the MC product (https://www.health.nsw.gov.au/pharmaceutical/Pages/unregistered-s8s.aspx).

SAS applications are processed at the federal level by the TGA and practitioners can now fill in one form which goes simultaneously to TGA (SAS application) and the state/territory health department (for approval to prescribe S8 MC products).

There is also a lack of harmonisation across Australian states and territories on which types of doctors can prescribe medicinal cannabis. For example, in Victoria General Practitioners may prescribe medicinal cannabis whilst in Tasmania, only specialists may do so. This potentially encourages doctor-shopping.

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

Canada is in a different position than Australia, having legalised recreational use in 2018 (see https://www.justice.gc.ca/eng/cj-jp/cannabis/). However, aspects of their regulatory scheme could be adopted. For example, under Canada's *Cannabis Act 2018* [5] patients may buy MC products from a provincially-licensed retailer; and in provinces and territories without a regulated retail framework, individuals may purchase MC online from federally-licensed producers [6]. The Canadian government has set up strict requirements for licensing of outlets [see Ref. 5]. Patients may take an authorisation for MC from their doctor to buy an MC product (though they do not need to). In addition, the Canadian government have set up a national tracking system to enable tracking of cannabis, prevent it being diverted to an illicit market or activity, and prevent illicit cannabis from being a course of supply in the legal market, detailed in Part 6 of Canada's Cannabis Act [5].

Australia could set up a system of licensing MC cannabis outlets and pharmacies would be ideally placed to take on this role.

If CBD is removed from the SUSMP (as is argued later in this submission), then other commercial outlets for CBD may also be possible, authorised by the government (and consideration could also be made about enabling online purchases from licensed outlets). This would do away with the current situation where MC companies require secure warehouses to store their products, and when a prescription reaches the pharmacy, the company must arrange delivery of that MC product to that pharmacy- a process that is time-consuming and costly to the MC company (and ultimately the patient).

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

High quality clinical training has been provided by ACNEM; in collaboration with the National Institute of Integrative Medicine (NIIM) and National Institute of Complementary Medicine (NICM) Health Research Centre in 2018, driven largely by NIIM's then Director of Education Professor Kylie O'Brien PhD. Professor O'Brien responded to a concern by ACNEM's founding director, Professor Ian Brighthope, that there was little training in MC for doctors. She set up the first two courses that received Category 1 Continuing Professional Development (CPD) points with the Royal Australasian College of General Practitioners (RACGP). These were delivered in Melbourne in May 2018 and Sydney later in the year.

Professor O'Brien, under Global Health Initiative (GHI) Australia, has since delivered a course focused on mental health and medicinal cannabis (which also received RACGP Category 1 CPD points), supported by ACNEM in July 2019 in Melbourne. GHI Australia, a not-for-profit organisation set up to focus on practitioner and public education in MC, is now officially partnering with ACNEM to deliver face-to-face training and online courses in MC. These will be accredited with the RACGP (the next face-to-face training course is in Brisbane 22/23 February 2020). These courses are unique in that they utilise active learning principles and involve practitioners working through case studies of particular medical conditions, so that doctors can learn how to prescribe MC products for such conditions, as well as have the knowledge to apply to prescribe under the SAS and AP Scheme. The courses cover the scientific evidence base for the use of MC in various conditions, safety aspects, and teach doctors how to safely prescribe it. The face-to-face courses to date have featured an international experts including Dr Sue Sisley (clinical researcher with expertise in PTSD), Dr Jeffrey Hergenrather MD and Dr Ray Gottsfeld MD, in addition to a growing team of local doctors and experts who form the teaching support team.

ACNEM and GHI Australia are both not-for-profit organisations which would benefit from government support to expand their training programs in MC. ACNEM is a highly respected college, operational for over 35 years, and the premier provider of postgraduate training to doctors and other allied healthcare practitioners in nutritional and environmental medicine. GHI Australia has the academic experience and expertise of one of Australia's leading cannabis experts, Professor Kylie O'Brien who has held senior teaching and learning positions at universities and in the private education sector. Together the two entities have the drive and expertise to create high quality, evidence-based training courses for doctors.

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

The endocannabinoid system (ECS) was only discovered in the early 1990s. Consequently, there is likely to be a significant cohort of medical practitioners who know very little about this important neuroregulatory system. It is unknown how much training in the ECS is offered in Australian medical courses. The comprehensive training courses run by GHI Australia and ACNEM cover the ECS as part of foundational knowledge on the first day of the two-day courses. The courses cover the scientific evidence base of MC for the treatment of various medical conditions and require attendees to apply this knowledge in working through case studies.

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

There are a number of sources of information for doctors and other healthcare practitioners about the uses of MC including on the websites of some MC companies in Australia. For example:

- Entoura is an exemplar of an MC company which provides evidence-based summaries (2-3 pages) for various medical conditions, researched and written by a respected academic and expert in the field of MC. Their website also has a growing library of journal articles indexed by condition.
- The Society of Cannabis Clinicians based in the US (https://www.cannabisclinicians.org/) also has a resource library
- GHI Australia has a summary and bank of journal articles which are also indexed by condition (www.ghiaustralia.org.au).

The difficulty with online resource libraries is keeping them up to date. This requires human resources to continue to add research papers to online libraries. GHI Australia and ACNEM are collaborating to develop online modules (single topics) and short courses focused on the evidence base of MC for various medical conditions. These will be available on the websites of ACNEM and GHI Australia and will be RACGP accredited (Category 2 CPD points would apply). The development of these online resources will be ongoing, however the speed at which these can be developed is limited by resources currently. It is intended that these modules and courses will be made available at a modest cost for healthcare practitioners worldwide.

Government support for the development of these MC resources would help improve and widen the scope of clinical conditions covered.

(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;

The issue is not simply that there is a shortage of Australian manufactured medicinal cannabis products that is impacting negatively on patient access. Whilst there are some companies which aim to be vertically integrated (growing, manufacturing and selling) in Australia, the majority of Australian MC companies import MC products and are likely to continue to do so. Not all MC companies want to grow/manufacture/distribute. There are significant delays in access to MC by patients due to the current regulatory system set up around importation of MC products which is not fit-for-purpose.

The lengthy timeframes for importation of MC products is impacting negatively on Australian MC companies. MC companies are required to lodge an import permit with the Office of Drug Control (ODC). The average time to process an import permit is at least 6 weeks and in a recent case, one company reports it has been waiting over 9 weeks. A conversation with one of the ODC officers indicated that priority is not given to MC because it is an 'unapproved good', and that they are understaffed and unable to handle the number of import permit applications (not just MC import applications). Once the import permit application is received, the import permit is posted to the MC company (which adds to delays due to the post). The Australian MC company must then courier the hard copy to their overseas supplier (which can take several days). The overseas exporting company must then include that permit in with the other documentation and the products when they are shipped. What should be a simple process is time-consuming and unnecessarily lengthy.

It is suggested that either the ODC is sufficiently staffed to handle such import permit applications, or that this responsibility and process be devolved to the states, specifically to an office set up to specifically handle import permit applications (and that these offices are sufficiently staffed to handle such applications).

With respect to the current shortage of Australian grown and manufactured MC products, one of the key issues is at the start of the chain, the growing of cannabis and hemp. Currently companies wishing to gain a MC growing licence can wait up to a year to gain this licence. This severely impacts on any potential MC growing businesses. Why it takes so long is unclear, however this is a disincentive for growers to enter the market. If there are difficulties with growing, then manufacturers will need to source raw material from overseas. Whilst this is possible, the cost of importing then adds to the higher end cost of the product. Moreover, there are apparently moves in place to collapse the current requirement for separate licences to grow, produce and manufacture into one licence (which is a good idea), the processing times must be improved greatly in order for this application system to not detrimentally affect Australian businesses.

Under Australia's *Hemp Industry Act 2008* 'low THC hemp' is defined as 'any plant of the genus Cannabis, by whatever name that plant may be called, that has a concentration of THC in its leaves and flowering heads of no more than 1%' [7]. In Australia, low THC hemp is grown for non-medical purposes and is used in the building, food (hemp seed products, which do not

contain cannabinoids), cosmeceutical, clothing and other industries. The fibre from mostly the stalks is what is used. However, the buds and flowers could also be used to make CBD oil, something that is not done in Australia. Under the current Act, MC products may not be produced under a licence issued under the *Hemp Industry Act 2008* [8]. To also utilise the buds/flowers to produce MC products from the same hemp crop would require an additional licence to grow medicinal cannabis, issued under the ODC.

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

The domestic regulated MC industry is in trouble. Anecdotally, many MC companies are not making money and instead are in danger of becoming financially unviable and closing. Since relatively few doctors are prescribing MC products, and the costs of MC products prohibitively expensive, the number of patients accessing MC legally is currently relatively small. Costs to the patient include not only the MC product cost but also the doctor consultation with significant out-of-pocket expense covered by the patient and often the cost of completing the SAS application passed onto the patient. Many MC companies are competing with each other for those few doctors prescribing MC to prescribe their MC product.

The costs of compliance with the importation regulatory system include not only direct and indirect (time cost) costs associated with applying for import permits. They also can include costs associated with establishing compliance with TGO93 (Therapeutic Goods Order 93) which sets out the quality assurance standards for imported MC products. Proving compliance with TGO93 is not straightforward as quality assurance standards are not harmonised with those in the US, Canada and to a lesser extent, Europe, which are major areas where Australian companies import from. For Australian MC companies importing from the US and Canada, it is particularly problematic as many laboratories in those countries do not test all of the items required under TGO93 and for particular items, may use a different standard (eg. a different cut-off level for presence of a particular heavy metal). At least one European laboratory will only deal with European companies and will not provide laboratory services to companies located outside of Europe.

Whilst there are some Australian laboratories which can carry out the required tests to the established compliance with TGO93, the practicalities and time-delays would be even more extensive. This would require an application for an import permit to import the sample (estimated 6-8 weeks), testing of the sample (which can take up to 3 weeks, for particular items such as aflatoxin), then if compliance is established, a second application to import the MC products (estimated 6-8 weeks), then the actual time taken to ship, clear customs, then be delivered to the MC company. The exporting company must sign a document stating compliance with the TGO93. This then negates the possibility of importing a shipment and only releasing it once compliance is confirmed in an Australian laboratory.

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

Patients who struggle to gain access to MC through Australia's regulatory regime due to financial barriers or difficulty finding a doctor open and trained to prescribe it are likely to be adversely impacted in terms of their wellbeing, both physical and mental. There are patients who are particularly sensitive to the active constituent profile and even manufacturing process of MC. Once they find a particular product that suits them, the potential negative impact is substantial if suddenly this particular product becomes unavailable, since substitution is not always possible. We are aware personally of one particular patient who accesses MC products from the US, and who was severely impacted last year when his MC became unavailable.

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

There is a lack of healthcare practitioners prescribing MC in Australia across the board, however this is likely to be even worse in rural and remote areas.

Some cannabis clinics are offering remote consultations which goes some way to address this issue. Getting to continuing professional development training on MC is likely to be more difficult for practitioners in rural and remote areas, making online courses even more important in the future.

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

Current prices of MC products are, for the most part, not affordable for the average Australian, let alone someone on a healthcare card or pension.

It is estimated that the cost of a 30ml bottle of MC is anywhere between $150 and $300. For patients with conditions such as epilepsy and cancer, the required daily dosage may be significantly higher than average, and costs could run into thousands of dollars per month.

(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;

It is unknown exactly how many Australian patients continue to rely on unregulated MC products, however there are several sources available in Australia, and anecdotally patients find these sources. In a news article published in August 2019, MC company Cannatrek was quoted as stating that an estimated 500,000 Australians bought medicinal cannabis on the black market each year to self-medicate [9], though it is unclear where they got this figure from. As far as we are aware, no national survey has been conducted. These unregulated sources are able to supply MC products at a much more affordable price than regulated MC products. As an example, a 50 ml bottle of CBD oil from an unregulated Australian distributor costs around $85. In Europe, one can buy a 30ml bottle of CBD oil for around 30 Euros.

Despite the fact that quality is not assured, price dictates affordability for many Australians. The danger associated with unregulated products is that they could contain contaminants such as heavy metals and pesticides, and that they may not contain the amount of active constituents they purport to.

(n) any related matters.

1. **TGO93 Stipulations about Contents of MC Products**

TGO93 states that MC products imported into Australia may not contain any active constituents derived from sources other than Cannabis sativa. It is unclear why this is so. In the US for example, some companies produce MC products where the terpenes, the essential oil components that give the plant its aroma, are derived from other plants (other plants contain many of the 200 terpenes found in Cannabis sativa). The reason that they do this is that the cost of terpenes derived from other plants are considerably cheaper than if derived from cannabis (this is likely to do with extraction and manufacturing processes). Thus, this stipulation in TGO93 effectively rules out importation of MC products which have been manufactured using terpenes derived from other plants.

2. **Scheduling of THC and CBD**

As previously suggested, there is no logical reason for CBD, one of the active constituents of MC, to be contained within Schedule 4 of the SUSMP. Cannabis is an herb, CBD (one of the better researched of the 120 phytocannabinoids in Cannabis) is derived from cannabis, and there are strains of cannabis (termed 'hemp' in the US) from which CBD oil is derived. The WHO 2018 report on CBD stated that CBD has a good safety profile, with low toxicity and no potential for dependence [10]. In June 2018, the WHO's Expert Committee on Drug Dependence (ECDD) recommended that preparations considered to be pure CBD not be placed under international drug control as the substance was not found to have psychoactive properties, and presents no potential for abuse or dependence [11].

CBD products should be treated the same as any other herbal medicine and regulated as a listed, assessed-listed or registered medicine on the SUSMP. One of the key reasons voiced by the Head of the TGA Professor John Skerritt, and in correspondence received by a MC industry collective from Minister Greg Hunt in November 2019 (in response to a position paper submitted to him), as to why CBD should remain on Schedule 4 is that CBD can interact with some anti-epileptic medications. Whilst this is theoretically possible [12] (since CBD can inhibit some cytochrome P450 enzymes that metabolise some pharmaceuticals) and some studies have shown this for medications such as valproate [13], other studies have not found evidence of increased adverse events due to drug-CBD interactions and have found that children have been able to reduce their anti-epileptic medication whilst on CBD [14, 15]. The fact is that there are many herbs which interact with many pharmaceuticals (for example St John's Wort, ginseng), and so CBD is nothing special in this regard. The literature indicates that such interactions with anti-epileptic medications are not common [12], and concerns about specific potential interactions could be handled via specific labelling, as is the case for other complementary medicines.

Scheduling of CBD on the SUSMP also serves to limit prescribing to healthcare practitioners who are not actually trained in herbal medicine, western medicine doctors. There is an argument that other healthcare practitioners, including registered Chinese medicine practitioners and western herbal medicine practitioners are well placed to prescribe CBD,

given that is an herb. If they were allowed to do so, this would help remove one of the barriers to patient access and lack of practitioners prescribing it. Such practitioners are more likely to prescribe CBD than western medical doctors, given that they are trained in herbal medicine and used to individualising medicines to patients.

Doctors seem to be reticent to prescribe for several reasons: they are unfamiliar with herbal medicines and how to prescribe them (cannabis is a herbal medicine and prescribing requires individualisation to the patient), they may believe there is a stigma attached to being a cannabis doctor, and some medical professional associations are not particularly supportive of MC. Herbal medicine practitioners are unlikely to have such qualms as it is simply another herb. In Australia, the standard of training for western herbal medicine and Chinese herbal medicine is a Bachelor degree. Chinese medicine practice is regulated under AHPRA, the same as western medicine. Western herbal medicine is self-regulated through professional associations such as ANTA and ATMS. Australia has a QA processes in place in relation to these two professions.

3. **Driving Laws and THC**

Currently under state/territory driving laws, it is an offence to have any amount of THC in the body, regardless of whether the driver is intoxicated or not. This law serves as a disincentive for patients to use products containing THC and for doctors to prescribe it (for fear of litigation). It is suggested that Australia adopts Canada's legal approach which is that it is only an offence to have THC in the body whilst driving if it is established that the driver is intoxicated. The 'Standard Impairment Test' could be applied during roadside drug-driving testing (see https://adf.org.au/insights/roadside-drug-testing/). The fact is that there are many other prescription medications more likely to impair driving than cannabis and THC. The potentially intoxicating effect of THC is dose-dependent. Some people on low doses will not become intoxicated at all. In addition, it is known that THC can stay in the body for several days, due to its lipophilic nature (it is readily taken up by fat cells then slowly released back into the circulation). The half-life of THC is estimated at 1.3 days for an infrequent user and 5-13 days for a frequent user [16].Thus, someone prescribed MC containing THC may have taken it hours or even days ago, and it may still be detected in the body.

4. **Supply Chain**

Currently if a patient is prescribed MC under the SAS or AP Schemes, permission must be granted by the state/territory health department to supply the MC medicine (and if the doctor prescribes under the SAS, TGA approval is needed). Once approved, the doctor writes a prescription which is then taken by the patient to a pharmacy. The pharmacy (unless they compound their own MC products) must then contact the MC company supplying the product and that company must arrange for it to be couriered from its secure warehouse to the pharmacy, before the patient can pick up the prescribed product. This adds another level of potential stress to patients who are already sick, as it likely requires three visits: one to the doctor, and two to the pharmacy. This issue would be alleviated by allowing pharmacies to stockpile MC products, just as they do any other prescription medicines.

5. **Overall Growth of the Industry**

The current system, from the commercial regulation, through to the prescribing system, serves to limit access to Australia and drive consumer prices up. It also serves to severely limit growth of Australian MC companies. Despite the Victorian Government's strategy to develop Victoria as a world class hub for high quality MC, the reality is that Victoria is nowhere near this goal. It is the experience of one of our senior members that there is a lack of staffing at the ODC level to process applications for import permits, which is a major cause of delays.

A recent conversation between one of ACNEM's members and a member of the Office of Medicinal Cannabis (Victoria, DHHS) suggests that the government staff member thought that once the growing and manufacturing industry was up and running successfully in Australia, import licences would be withdrawn by the TGA and that the only reason importation was allowed was simply to allow supply until such time as Australia was growing and manufacturing its own products. Whilst the anti-competitive nature of this would serve to ensure that this would be able to occur in this country, it is concerning that this was even voiced by someone in the government. It may simply indicate a lack of understanding of one individual employed by the government, however it may also reflect an unsupportive attitude towards an important part of the MC industry now and into the future- the import industry. Not all MC companies want to be vertically integrated and grow/manufacture/distribute. The MC import industry should be a key part of government strategy for development of the MC industry, in addition to development of a local growing and manufacturing industry.

In summary, there needs to be a much better understanding of the roadblocks to the commercial MC industry, as those are the reasons why the MC industry is not growing in this country, and also a key reason why MC product prices are high. The costs of the commercial/industry regulatory system, which is unnecessarily bureaucratic and costly, threaten the growth of the commercial industry, and ultimately the costs are being passed onto the consumer. A systematic approach to the whole industry needs to be taken, with all components and their inter-relationships clearly integrated. Government needs to be responsive to the concerns of members of the MC industry, not defensive and to work in partnership with experts to improve access to MC to those in need.

References

1. Introduction to Medicinal Cannabis Regulation in Australia. TGA, 29 Oct 2019. Available at:https://www.tga.gov.au/blogs/tga-topics/introduction-medicinal-cannabis-regulation-australia [accessed 18 Jan 2020]
2. National Academies of Sciences, Engineering and Medicine. The Health Effects of Cannabis and Cannabinoids. The National Academies Press, Washington DC, 2017.
3. TGA. Guidance for the Use of Medicinal Cannabis in Australia: Overview. TGA, Version 1, December 2017. Available at: https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-overview [accessed 18 Jan 2020]
4. TGA. Access to Medicinal Cannabis Products. TGA, 13 Jan 2020. Available at: https://www.tga.gov.au/access-medicinal-cannabis-products-1 [accessed 18 Jan 2020]
5. Cannabis Act 2018. https://laws-lois.justice.gc.ca/eng/acts/C-24.5/ [accessed 18 Jan 2020]
6. Government of Canada Dept of Justice. Cannabis Legalization and Regulation. Available at: https://www.justice.gc.ca/eng/cj-jp/cannabis/?mc_cid=44954a3229&mc_eid=%5bUNIQID%5d [accessed 18 Jan 2020]
7. Hemp Industry Act 2008. Available at: https://legislation.nsw.gov.au/#/view/act/2008/58 [accessed 18 Jan 2020]
8. NSW Government Dept of Primary Industries. Growing Low-THC Hemp in NSW- Frequently Asked Questions. Jan 2019. Available at: https://www.dpi.nsw.gov.au/__data/assets/pdf_file/0004/431095/growing-low-thc-hemp-in-nsw-faq.pdf [accessed 18 Jan 2020]
9. Tuffield R, Ortolan M. Medicinal cannabis company to build one of the world's largest production facilities in the world. ABC Shepparton, 22 Aug 2019. Available at: https://www.abc.net.au/news/2019-08-22/shepparton-taps-into-budding-cannabis-market/11436218 [accessed 18 Jan 2020]
10. WHO World Health Organization (WHO). World Health Organization Expert Committee on Drug Dependence. Cannabidiol (CBD) Critical Review Report. Expert Committee on Drug Dependence Fortieth Meeting Geneva, 4-7 June 2018. World Health Organization (WHO), 2018c. Available at URL: https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf
11. World Health Organization (WHO). Cannabis Review Questions and Answers. World Health Organization (WHO), 2018. Available at URL: http://www.who.int/medicines/access/controlledsubstances/Cannabis_Review_QA_26July2018.pdf [accessed 9 October 2018]
12. Devinsky O et al. Cannabidiol: pharmacology and potential therapeutic role in epilepsy and other neuropsychiatric disorders. Epilepsia 2014 Jun;55(6):791-802.
13. Gaston TE, Bebin EM, Cutter GR et al. Interactions between cannabidiol and commonly used antiepileptic drugs. Epilepsia 2017; 58(9):1586-1592.
14. Hussain SA et al. Perceived efficacy of cannabidiol-enriched cannabis extracts for treatment of pediatric epilepsy: A potential role for infantile spasms and Lennox-Gastaut syndrome. Epilepsy Behav 2015; 47():138-41.
15. Aguirre-Velazquez CG. Report from a survey of parents regarding the use of cannabidiol (medicinal cannabis) in Mexican children with refractory epilepsy. Neurol Res Int 2017; 2985729

16. Smith-Kielland A, Skuterud B, Morland J. Urinary excretion of 11-nor-9-carboxy-delta9-tetrahydrocannabinol and cannabinoids in frequent and infrequent drug users. J Anal Toxicol 1999; 23: 323-332.