# Medicinal Cannabis Industry Round Table Position Paper: Medicinal Cannabis

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## EXECUTIVE SUMMARY

A round table meeting of representatives from the medicinal cannabis industry met at Victorian Parliament House on 1 October 2018 to discuss some of the key issues within the industry. Medicinal cannabis, Cannabis Sativa, is an herbal medicine with more than 750 secondary metabolites, including over 120 cannabinoids. Tetrahydrocannabinol (THC) and cannabidiol (CBD) are two of the main cannabinoids. THC has intoxicant ability, whereas the other cannabinoids do not. There are many different cultivars of C. sativa, with varying amounts of THC and CBD, that have been grown for the medicinal cannabis market. There is evidence of efficacy for medicinal cannabis in a wide range of medical conditions including chronic pain, epilepsy, chemotherapy-induced nausea and vomiting, spasticity associated with multiple sclerosis and sleep disorders, and many more.

A key issue identified was difficulties in patient access to medicinal cannabis. It is estimated that over 100,000 patients are accessing medicinal cannabis via the black market in Australia. Difficulties in access relate to Australia's complex regulatory system around medicinal cannabis, and a lack of medical practitioners prescribing it. This, in turn is likely to be due to lack of knowledge about medicinal cannabis and the onerous process of obtaining approval to prescribe it. Currently, CBD and THC are included in Schedules 4 and 8 respectively of the Standard for the Uniform Prescribing of Medicines and Poisons (SUSMP). States and territories generally adopt the Schedules and appendices of the SUSMP. Consequently, CBD and THC may only be prescribed by medical practitioners, typically via the Special Access Scheme or the Authorised Prescriber Scheme. State and territory-based health department approval is also necessary. In June 2018, the WHO's Expert Committee on Drug Dependence recommended that pure CBD preparations should not be placed under international drug control as CBD does not have psychoactive/intoxicant properties, and presents no potential for abuse or dependence.

Another key issue identified is that it is an offence to drive with any amount of THC in the body, regardless of whether it has been prescribed or not. This is a strong disincentive for patients to take medicinal cannabis containing THC. If chronic pain alone is considered in Australia, the potential for alleviation of suffering through ready access to medicinal cannabis is enormous.

Victoria aims to become the medicinal cannabis hub of Australia, with ambitious goals set out in its *Victorian Industry Development Plan.* However, lack of access to medicinal cannabis products has the potential to cause substantial harm to the Victorian and Australian medicinal cannabis industry.

Key recommendations endorsed by a range of key stakeholders are as follows:

- Off-schedule CBD: remove CBD from Schedule 4 of the SUSMP (and in Victoria, the Victorian Poisons List) and regulate proprietary forms of CBD products as complementary medicines via the ARTG. Down-schedule THC-containing products with no more than 30mg/ml THC to Schedule 4 of the SUSMP.

- Decriminalise the presence of THC in the body whilst driving by patients holding a prescription for medicinal cannabis product(s) containing THC provided the individual is not impaired. For patients with a prescription for medicinal cannabis, apply 'Standard Impairment Test' during road-side drug-driving testing. For all others, the standard road laws in relation to THC apply.

- Develop a system for licensing of healthcare practitioners who are appropriately trained and certified in the safe prescribing of medicinal cannabis.

- Further develop education and clinical practice guidelines: capitalise on existing expertise in medicinal cannabis education to further develop practitioner education, develop public education and awareness and develop clinical practice guidelines.

## 1.0 Introduction

A round table meeting of representatives from the medicinal cannabis industry was held at Victorian Parliament House on 1 October 2018. The meeting included consumer representation, leaders from medicinal cannabis growing, manufacturing and retail companies, education, clinical practice, business development, research and a Member of The Legislative Council in the Victorian parliament.

The following sets out the key issues identified in relation to the medicinal cannabis industry in Australia, options for addressing these, and recommendations to government.

## 1. Background

Medicinal cannabis is the judicious use of cannabis which has been cultivated or manufactured for the treatment of medical conditions and to promote wellness. Medicinal cannabis can include, by definition, the raw herb, as well as proprietary forms of medicines which include whole herb products, extracts of active constituents of the Cannabis sativa plant, as well as synthetic cannabinoid products (which are considered pharmaceuticals). Therefore, for future reference, throughout this discussion when we refer to medicinal cannabis, we refer both to cannabis as a complementary medicine and a pharmaceutical medicine. Both forms of medicine have a valid place in health and medical care.

Major proprietary forms of medicinal cannabis include cannabis-based liquid extracts (eg. nabiximols), phytocannabinoid botanicals (dense cannabis extracts manufactured as capsules, pills, sublingual sprays, suppositories, transdermal patches and topical ointments) and single molecule drugs: synthetic or semi-synthetic prescription drugs (eg. nabilone, dronabinol which are FDA-approved). Medicinal cannabis products may contain a mixture of two of the main active constituents, tetrahydrocannabinol (THC) and cannabidiol (CBD) in varying ratios, or CBD alone (no THC). Some products may contain other cannabinoids and/or terpenes and other plant constituents. This paper is concerned in particular with proprietary forms of medicinal cannabis, rather than raw cannabis products.

### 2. Cannabis is a Plant with Medicinal Properties

Cannabis is plant and an herbal medicine. There has been debate within the literature as to the taxonomy or nomenclature of Cannabis. The genus is Cannabis and the family Cannabaceae (Pollio 2016). A taxonomy adopted by Small and Cronquist, based on combining morphological and chemical characters (fruit morphology and THC) recognises four distinct taxa of the species Cannabis sativa. There are two main subspecies: C sativa subspecies sativa and C sativa subspecies indica, each of which have two different varietates (Pollio 2016).

The *varietates* belonging to the subspecies sativa[1] are common in North America, Europe, and Asia, show a limited intoxicant potential and are cultivated for fibre and oil. In contrast the *varietates* of the subspecies indica [2]have high intoxicant potential (due to the presence of THC) and grow mainly in the Asiatic Continent (Pollio 2016; WHO 2018a). There are hundreds of 'cultivars' of the cannabis plant, with varying amounts of THC and CBD, that have been bred for the medicinal cannabis market.

Cannabis sativa has over more than 750 different secondary metabolites, including cannabinoids and other constituents (eg. terpenes, phenols, flavonoids and many others) which are responsible for many of the plant's beneficial effects, including analgesic, anti-nausea/vomiting, anti-inflammatory, anti-oxidant and neuroprotective effects (Upton et al. 2013; Bridgeman et al. 2017; Pertwee et al. 2015). Synergism between the active constituents is likely to be responsible for its therapeutic efficacy

[1] (*Cannabis sativa* L. subsp. *sativa* var. *sativa and Cannabis sativa* L. subsp. *sativa* var. *spontanea* Vavilov)
[2] (*Cannabis sativa* L. subsp. *indica* Small & Cronquist var. *indica* (Lam) Wehmer; and *Cannabis sativa* L. subsp. *indica* Small & Cronquist var. *kafiristanica* (Vavilov) Small & Cronquist)

and mitigation of side effects of the dominant active ingredients (McPartland and Russo 2001). There are over 120 individual cannabinoids (WHO 2018a), the best researched being THC which has intoxicant effects and CBD which has no intoxicant ability (Pertwee et al. 2015; Lafaye et al. 2017). Although much of the research and development has focused on THC and CBD, there are many other cannabinoids with therapeutic effects, and the terpenes also have their own positive effects on the body including anti-inflammatory, anxiolytic, inducing apoptosis in breast cancer cells, broad-spectrum antibiotic and others (Russo et al. 2011).

**2.2 Scientific Evidence of Efficacy**

There is scientific evidence of the benefits of medicinal cannabis in a range of medical conditions. A comprehensive US report on medicinal cannabis published in 2017 states that there is conclusive or substantial evidence that medicinal cannabis or cannabinoids are effective for the treatment of chronic pain, chemotherapy-induced nausea and vomiting, and patient-reported relief of spasticity associated with multiple sclerosis, and that there was a moderate level of evidence for its efficacy in improving short term outcomes in individuals with sleep disorders associated with particular conditions[3] (National Academies of Science, Engineering and Medicine 2017). Other conditions where medicinal cannabis may be efficacious include: PTSD, diabetes, cancer, anxiety, epilepsy, inflammatory bowel disease, neurodegenerative diseases (including Parkinson's Disease), traumatic brain injury and many others (Bridgeman et al. 2017; National Academies of Science, Engineering and Medicine 2017; Lotan et al. 2014; Gorka et al. 2014; Whiting et al. 2015; Crippa et al. 2011; de Mello Schier et al. 2012). In 2017 14 medical conditions were approved by state legislatures in the US as qualifying conditions for MC, the most common being relief of symptoms associated with cancer, glaucoma, HIV and multiple sclerosis (Bridgeman et al. 2017).

Research indicates that the cannabinoids and terpenes have a wide range of beneficial actions including but not limited to: anti-inflammatory, anti-oxidant, neuroprotective, anxiolytic, anti-depressant/mood elevation and sedative (Upton et al. 2013; Bridgeman et al. 2017; Pertwee et al. 2015; Whiting et al. 2015; Crippa et al. 2011; de Mello Schier et al. 2012). Preclinical research indicates that the cannabinoids also have anti-cancer actions, acting on several of the pathways associated with cancer: reducing inflammation, inducing apoptosis, inducing cell-cycle arrest, inhibiting cell growth and cancer cell invasion, and targeting angiogenesis (new blood vessel formation) and cell migration (De Marzo et al. 2006; Guindon & Hohmann 2011). Preclinical research also indicates that cannabinoids synergise with chemotherapy drugs, improving efficacy (Donadelli et al. 2011; Torres et al. 2011).

Medicinal cannabis has been found to alleviate suffering in the palliative care setting. A study was conducted in 2790 late stage cancer patients taking medicinal cannabis for alleviation of sleep problems, pain, weakness, nausea and lack of appetite. After 6 month's follow-up, 24.9% had died, and 18.8% stopped treatment. Of the remaining, 1211 (60.6%) responded; 95.9% reported an improvement. Use was associated with decreased use of pain medication, reduction in opioid use, and minor side effects that were easy to cope with (Bar-Lev Schleider et al. 2018).

**2.3 Cannabidiol (CBD)**

CBD is gaining particular interest due to its good safety profile, lack of intoxicant effects and evidence of a range of positive health benefits. Recent studies have shown that CBD is effective in the treatment

[3] Improving short term outcomes in individuals with sleep disturbance associated with: obstructive sleep apnoea, fibromyalgia, chronic pain, and multiple sclerosis.

of epilepsy and Dravet Syndrome (WHO 2017; Devinsky et al. 2017). It also has the following properties: neuroprotective, antiepileptic, hypoxia-ischemia, anxiolytic, antipsychotic, analgesic, anti-inflammatory, anti-asthmatic, and antitumor (WHO 2017). A review of the clinical indications of CBD reported that CBD may have therapeutic benefits in the following conditions, based mostly on findings from preclinical research: pain, multiple sclerosis, Parkinson's Disease, Alzheimer's Disease, Huntington's Disease, hypoxia-ischaemia injury, psychosis, anxiety, depression, cancer, nausea, inflammatory disease, inflammatory bowel and Crohn's disease, rheumatoid arthritis, infection, cardiovascular diseases and diabetic complications (Pisanti et al. 2017).

A WHO Expert Committee on Drug Dependence pre-report on CBD published in 2017 concluded that CBD is *'generally well tolerated with a good safety profile'* and that: *'To date, there is no evidence of recreational use of CBD or any public health related problems associated with the use of pure CBD* (WHO 2017). 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 (WHO 2018b).

**2.4 Tetrahydrocannabinol (THC)**

THC is one of over 120 cannabinoids, and one of the best researched. It is the (only) cannabinoid responsible for the intoxicant actions of cannabis. Pure THC products or synthetic THC products (eg. dronabinol) are likely to be quite different to whole plant extracts containing THC and other cannabinoids plus terpenes (which have themselves been shown to have a range of beneficial actions). There is evidence that CBD, for example, is able to moderate the negative effects of THC (Niesink and van Laar 2013).

The WHO Pre-Report on THC indicates a range of studies conducted on pure THC and synthetic THC with a range of outcomes (WHO 2018c). For example, studies of dronabinol indicate efficacy in the treatment of chronic pain (as an add-on medication), spasticity associated with MS, non-cardiac chest pain, obstructive sleep apnea, opioid use disorder (decreased opioid withdrawal symptoms), and Tourette Syndrome. Dronabinol was efficacious in stimulating appetite in people with HIV/AIDS infection, was associated with weight gain in anorexia nervosa patients and was found to decrease anxiety (secondary outcome measure) in pain patients (WHO 2018c).

THC binds with CB1 receptors (cannabinoid receptors) in the central nervous system (i.e. brain, as well as elsewhere in the body) and has potential psychoactive actions which are beneficial in particular medical conditions. For example, research indicates that THC may reduce threat perception or enhance socio-emotional regulation during socio-emotional threat in healthy adults (Gorka et al. 2014). In post-traumatic stress disorder, THC can enhance extinction learning (Rabinak et al. 2013; Das et al. 2013). Extinction is 'the learned inhibition of retrieval of previously acquired responses' (Furini et al. 2014). Persistence of fear in the absence of an imminent threat is characteristic of anxiety disorders, and impaired ability to acquire or retrieve extinction learning may underlie pathological anxiety (Hartley & Phelps, no date). Research indicates that smoking cannabis (which contains THC) was associated with significant decreases in depression, anxiety and stress, with high THC (eg. > 26.5%)/high CBD (eg. > 11%) cannabis best for reducing perceived symptoms of stress (Cuttler et al. 2018).

The concern around THC is related to its potential *intoxicant* ability, and this will relate to how cannabis is used, dosage, and individual factors including how it is metabolized within the body. The WHO states that THC has very similar pharmacological and subjective effects to cannabis. Side effects asso-

ciated with THC that may be experienced in some people include: euphoria, laughter, increased appetite, dry mouth, occasional dizziness, and enhanced visual, olfactory and auditory perceptions. It can also cause nausea and vomiting in some users. The effects of THC are mostly subject to tolerance with repeated exposure. THC can also cause subtle cognitive deficits in some people, such as impaired attention and short-term memory impairment. In some, higher doses may also cause anxiety, panic, confusion, and disorientation. It can also provoke transient psychosis-like psychological phenomena in some healthy people, though these effects were found to be modest in magnitude and reversible (WHO 2018c).

A key point is that smoking cannabis recreationally is not the same as taking medicinal cannabis which has been prescribed by a qualified healthcare practitioner, titrated to the appropriate dose for that individual. Much of the literature around safety relates to its recreational use.

It is worth noting that in terms of long-term safety, the WHO has stated that: *'RCTs in which ∆ 9 -THC has been sometimes given daily to participants for periods of years, generally report low to moderate toxicity and a low incidence of serious adverse events'* (WHO 2018c).

**2.5 Chronic Pain in Australia**

Chronic pain is a clear medical indication for the use of medicinal cannabis. Chronic pain is the most common reason patients seek medical help. One in five Australians live with chronic pain, including adolescents and children, and prevalence increases to one in three in people over 65 years of age (Pain Australia, no date). The economic cost of chronic pain is huge. It is the third most-costly health condition after cardiovascular disease and musculoskeletal conditions (which are also associated with chronic pain) (Pain Australia, no date). The total cost to the community has been estimated at $34.3 billion (Pain Australia 2016). The National Pain Strategy Goals include: *'People in pain as a national health priority'* and *'Access to interdisciplinary care at all levels of the health system'* (Pain Australia 2016).

The National Academies of Science, Engineering and Medicine's 2017 report, based on evidence from systematic reviews and randomised controlled trials, states that there is conclusive or substantial evidence that cannabis or cannabinoids are effective in the treatment of chronic pain (National Academies of Sciences, Engineering and Medicine 2017).

*Opioid Crisis and Potential Solution*

Australia, like the US, has an opioid crisis on its hands. According to a 2018 TGA Consultation paper, *'Levels of prescription opioid overdose, including accidental overdose are at record levels in Australia and internationally*'. The TGA paper reports that *'between 2011 and 2015 there were 2145 deaths associated with oxycodone, morphine, codeine, fentanyl, tramadol and/or pethidine compared with 985 due to heroin'* (TGA 2018).

Evidence from the US suggests that legalisation of medicinal cannabis is associated with reduced hospitalisations related to opioids. A study published in 2017 that examined the associations between state medical marijuana policies and hospitalisations related to marijuana and opioid pain relievers (OPR) found that: '*Medical marijuana legalization was associated with 23% (p=0.008) and 13% (p=0.025) reductions in hospitalizations related to opioid dependence or abuse and OPR overdose, respectively*' (Shi 2017). The researcher concluded that: '*Medical marijuana policies were significantly associated with reduced OPR-related hospitalizations but had no associations with marijuana-related hospitalizations. Given the epidemic of problematic use of OPR, future investigation is needed to explore the causal pathways of these findings'* (Shi 2017).

The use of medicinal cannabis for the treatment of chronic pain may contribute to solving the opioid crisis in Australia.

**2.6 Consumer Rights and Self-Care in Health**

Self-care has been defined by the WHO as *'the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider'* (WHO 2014). This definition recognises the active role of the patient in their own healthcare, as opposed to being a passive recipient of treatment. The report *The State of Self Care In Australia* states that: *'A healthy population is achieved through a functional relationship between active and informed individuals, health care services that empower and support people, and governments that invest in the capabilities of individuals and communities to look after their health '* (Australian Health Policy Collaboration 2018). It is estimated that over 100,000 Australian patients are accessing medicinal cannabis through the black market. Rather than being applauded for taking their health into their hands, these people risk a jail term or at the very least a fine and/or police record.

In Australia, patient groups have provided the National Institute of Integrative Medicine (NIIM) with a list of their needs and priorities for action. This has already guided the development of the medicinal cannabis course developed by NIIM and ACNEM, and will inform future educational activities.

Patients have the right to timely access to medicines of their choice. If a patient, in consultation with their healthcare provider, wants medicinal cannabis as a treatment of first choice, that should be their right. Almost 70% of Australians are using some form of complementary medicine (Xue et al. 2007). Australians are already demonstrating how they choose to manage their health.

In the US, 31 states have legalized the use of medicinal cannabis (ProCon.org 2018). Canada has recently legalized adult use cannabis, the law coming into effect on the 17th October, 2018 (Government of Canada, no date).

**2.7 Patient Advocacy in Australia**

There are key patient advocacy groups which have been actively working to draw attention to the need for the Australian government to improve access to medicinal cannabis. These include United in Compassion (UIC) and Epilepsy Action Australia. The Australian Medicinal Cannabis Alliance and United in Compassion have developed a joint position statement (see https://www.unitedincompassion.com.au/amca ). Two key principles are that it:

1. Considers that the legislation/regulation concerning medicinal cannabis access should be based on what is best for patients as a medical consideration rather than a political consideration;
2. Recognises human rights and medical necessity as a valid argument for greater accessibility of medicinal cannabis.

It also calls for provisions to allow driving for patients using medically prescribed cannabis when there is no evidence of impairment (Point 13, Position Statement, https://www.unitedincompassion.com.au/amca).

**2.8 The Medicinal Cannabis Growing and Manufacturing Industry in Victoria**

Victoria has set itself up to be a major centre for the growing and development of medicinal cannabis. The *Victorian Industry Development Plan- Developing a Medicinal Cannabis Industry in Victoria 2018-*

*2021* sets out the goals for the development of this industry (Agriculture Victoria 2018). The plan is ambitious, and seeks to position Victoria as the 'Australian hub for medicinal cannabis innovation', with projections of 500 new Victorian jobs along the supply chain from cultivation to sales by 2028 (Agriculture Victoria 2018). The Plan also states that Victoria is well positioned to grow the industry through global exports and that with its existing agriculture research and development facilities and large life sciences cluster, Victoria is an attractive location for international investment (Agriculture Victoria 2018).

In order to support the interests of growers and manufacturers, several industry groups have formed within Australia. Industry groups with an interest in hemp and cannabis include: the Australian Industrial Hemp Alliance, Complementary Medicines Australia, Medicinal Cannabis Industry Association and the Medical Cannabis Council.

## 3.0 The Issues in Australia

### 3.1 Issue 1: Lack of Timely Patient Access to Medicinal Cannabis

An estimated 100,000-120,000 Australians are accessing medicinal cannabis (MC) on the black market. Access to medicinal cannabis is difficult in Australia due to a complex regulatory scheme which is not fit-for-purpose. Due to the inclusion of CBD and THC on Schedules 4 and 8 respectively of the Standard for the Uniform Prescribing of Medicines and Poisons (SUSMP), currently only medical practitioners are able to prescribe it. Other professions regulated via statutory regulation which conceivably may be well-placed to prescribe certain medicinal cannabis products are nurses and Chinese herbal medicine practitioners.

A key problem is that there are not many medical practitioners prescribing medicinal cannabis in Australia currently. This is likely to be due to the difficult process involved in applying to prescribe it and lack of knowledge about this plant medicine.

*Difficult Prescribing Process*

For medical practitioners to prescribe medicinal cannabis products, they must apply to the Therapeutic Goods Administration via the Special Access Schemes or the Authorised Prescriber Scheme. The Special Access Scheme B requires a medical practitioner to apply to prescribe a specific product for a specific patient. Under the TGA's Authorised Prescriber Scheme, a medical practitioner may seek approval to prescribe specific medicinal cannabis products (considered 'unapproved goods' under the TGA) for a specific class of patient or medical condition. Both systems require the medical practitioner to also apply to their state/territory health department to access a Schedule 8 medicine.

General practitioner Assoc. Prof. Vicki Kotsirilos drew attention to the difficult process in 2017 in an article published on the Royal Australian College of General Practitioners' website. She stated that *'The application process for a medicinal cannabis permit is onerous, lengthy and difficult for GPs, as it involved obtaining two permits- from the TGA Special Access Scheme and the relevant state poisons department for a schedule 8 permit. This has been a deterrent for GPs to prescribe medicinal cannabis for suitable patients'* (Kotsirilos 2018).

In relation to the Special Access Schemes, most states and territories have now developed one form which goes to the TGA and health department (rather than two separate processes as was the case until recently), cutting down on some of the paperwork.

In order to become an Authorised Prescriber of medicinal cannabis under the TGA's Authorised Prescriber Scheme, a medical practitioner must apply to a Human Research Ethics Committee (HREC) or

Specialist College for approval first, then once approved there, apply to the TGA. The amount of paperwork is substantial. In addition, if they later decide they would like to use a different medicinal cannabis product, they must apply again through the HREC and TGA (for approval). They also must still apply to their state/territory health department for use of a Schedule 8 medicine (THC containing product). This is both costly and time-consuming.

A further issue is that the TGA's stance is that: *'medicinal cannabis is not considered a first-line therapy for any indication'*. The TGA's document, *Guidance for the Use of Medicinal Cannabis in Australia: Overview*, states that *'At this time, we suggest that the use of medicinal cannabis may be considered only when registered medicines have been tried and proven unsuccessful in managing the patient's symptoms or medical condition' (TGA 2017).* This stance may also be a deterrent for some practitioners to prescribe it. Moreover, this stance does not respect the rights of the patient to choose how they want to manage their health, nor the autonomy of the medical practitioner to decide what is the right, best or optimal therapy for the patient. It is not consistent with the World Medical Association's Declaration of Geneva (the Australian Medical Association is a signatory to the World Medical Association) which specifies respect for the autonomy (and dignity) of the patient, and positions the health and wellbeing of the patient as the first consideration of a doctor (World Medical Association 2018). Decisions about treatment should be made by the patient and healthcare practitioner together.

*Lack of Knowledge About Medicinal Cannabis*

The lack of medical practitioners prescribing medicinal cannabis is likely also to be due to lack of knowledge about medicinal cannabis, including its evidence base. Training in medicinal cannabis does not currently form part of undergraduate medical curricula. There is a two-day medicinal cannabis course that was developed early in 2018 to train doctors in the prescribing of medicinal cannabis that has been approved by the Royal Australian College of General Practitioners (RACGP) for Category 1 Continuing Professional Development points (www.medicinalcannabiseducation.org.au). This evidence-based, active learning course was developed by the National Institute of Integrative Medicine (NIIM), the Australasian College of Nutritional and Environmental Medicine (ACNEM) and the National Institute of Complementary Medicine (NICM). There are a few other smaller courses also being run by other individuals.

**3.2 Issue 2: Current Scheduling of Cannabidiol (CBD) and Tetrahydrocannabinol (THC)**

CBD is currently contained within Schedule 4 of the Standard for the Uniform Prescribing of Medicines and Poisons (SUSMP). Schedule 4 is defined as follows: '***Prescription Only Medicine****, or* ***Prescription Animal Remedy*** *– Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription*' (Poisons Standard 2018).

States and Territories drugs and poisons legislation typically adopts the various Schedules and Appendices of the SUSMP. Drugs and Poisons legislation is state/territory-based. There is substantial scientific evidence that CBD has a range of beneficial effects, described earlier. Whilst there will always be a call for 'more research' in any field of medicine, there is already a substantial body of research that CBD (as well as cannabis more generally) is efficacious in a range of conditions. Importantly, CBD has been shown to be safe. As discussed previously, the WHO have recommended that CBD should not be scheduled (WHO 2018).

Given the findings of the WHO report, the evidence does not support continuing to keep CBD on Schedule 4 of the SUSMP. Australia has a world-class, stringent system for regulating complementary medicines via listing or registering on the Australian Register of Therapeutic Goods.

THC is current contained with Schedule 8 of the SUSMP. This Schedule is defined as: *'**Controlled Drug**: Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence'* (Poisons Standard 2018).

The WHO Expert Committee on Drug Dependence Pre-Review on Delta-9-Tetrahydrocannabinol has reviewed the potential for abuse. According to this report, *'human studies relevant to the abuse potential of pure or synthetic ∆ 9 -THC (i.e., excluding cannabis and plant-derived extracts) have used dronabinol and an oral route of administration'*. It states that: *'A multi-method review that incorporated findings from the scientific and product safety literature as well as interviews with physicians and perusal of the popular press revealed little evidence that oral dronabinol was used for non-medical purposes'* (WHO 2018c).

The WHO Expert Committee on Drug Dependence also reviewed the potential for dependence or addiction in relation to THC. The report describes that some earlier studies using marijuana cigarettes have shown withdrawal symptoms after cessation, however most are alleviated within 96 hours of cessation. Later studies using lower doses of THC (80-120mg daily, p.o.) also showed development of tolerance to effects of THC and symptoms of withdrawal on abrupt cessation after a four-day repeated dosing regime, however when the duration of the dosing regime was shortened to three days, development of tolerance and physical dependence no longer occurred. Importantly the report states that: *'Notably, in all of these laboratory-based studies, oral ∆ 9-THC doses greatly exceeded recommended dronabinol dosage for the treatment of AIDS associated wasting and chemotherapy-induced nausea'* (WHO 2018c).

The WHO Expert Committee on Drug Dependence Pre-Review on Delta-9-Tetrahydrocannabinol states that the *'toxicity of ∆ 9-THC is very low compared to most other recreational and pharmaceutical drugs'* and that *'a lethal dose of lethal dose in a 70 kg human would be approximately 4 g and that such a dose could not be realistically achieved in a human following oral consumption, smoking or vaporising the substance, as Δ-9-THC has a large margin of safety'*. It also states that *'Absence of mortality with Δ- 9 -THC may reflect low density of CB1 receptors in brainstem regions that control vital cardiovascular or respiratory functions'* (WHO 2018c).

There is a potential for dependency, and this may be related to higher than normal doses and longer treatment dosing regimes (that may be required for more serious medical conditions). THC has been demonstrated to have low toxicity, as set out above. In contrast, anti-depressant and anxiolytic drugs which are Schedule 4 drugs, have been associated with suicide ideation and self-harm. It is the responsibility of the treating doctor to ensure they appropriately monitor their patients, as they would with any psychoactive medication.

Consideration could be given to rescheduling THC to Schedule 4, in line with other pharmaceutical drugs such as anti-depressants. An application has been submitted to the TGA recently to reschedule nabiximols as a Schedule 4 medicine, based on it containing not more than 30mg/ml of THC. Clinical guidelines should be developed to guide medical practitioners on dosage regimes.

**3.3 Issue 3: Driving Laws**

Under Australian state and territory-based driving laws, it is an offence to have any amount of THC in the body, regardless of whether it was prescribed by a medical practitioner or not. This presents problems for individuals who have been prescribed medicinal cannabis containing THC, as the THC can remain in the body for several days. Having THC in the body does not equate with intoxication or impairment. Yet, many patients are likely to be put off taking prescribed medicinal cannabis products containing THC because of the risk of being pulled over in their car for a random drug test.

A recent study of multiple sclerosis patients found that an oromucosal spray of THC and CBD did not impair driving performance and did not show any evidence of an increase in driving accidents. Patients reported an improvement in driving ability, speculated to be due to reduced spasticity and/or better cognitive function (Celius and Villa 2018).

Canada have addressed this issue as part of their legalisation of adult use of cannabis by requiring that it must be established that a person is impaired by cannabis for it to be an offence. Drug-impaired driving is an offence in Canada. Police are trained to detect if someone is driving under the influence of a drug via 'Standard Field Sobriety Testing' and via 'Drug Recognition Experts'. New legislation also allows law enforcement to use drug screening devices which can detect the presence of several drugs including THC from cannabis (Government of Canada, no date).

### 3.4 Issue 4: The Medicinal Cannabis Commercial Industry

Australia has set itself up to become a force in the medicinal cannabis growing and production industries on the world stage. Australia's GMP processes are amongst the most rigorous in the world. Australia already enjoys a very favourable reputation in the supplements market because of the quality assurance processes demanded by the TGA. However, if Australians can't get ready access to medicinal cannabis products, this is going to severely hamper the development of this industry and as a consequence, the Australian medicinal cannabis industry will lag further behind other countries. Stock prices are likely to fall as a result of lack of confidence in the local market. Without certainty about patient access, companies are less likely to invest in developing the medicinal cannabis industry in Australia. This will have a flow on effect on job growth. Australia is already well behind Canada and the United States.

The *Victorian Industry Development Plan- Developing a Medicinal Cannabis Industry in Victoria 2018-2021* states that *'By building on our existing strengths, such as Victoria's advanced manufacturing and med-tech capabilities, we are well-placed to develop a responsible industry that provides patients with reliable, effective, life-changing medicines'* (Agriculture Victoria 2018).

It further states that *'This competitive new Victorian industry will contribute to the productivity of the state and the creation of new jobs along the industry's supply chain'*. It goes on to state that *'A thriving medicinal cannabis industry has the potential to create up to 500 new Victorian jobs along the supply chain, from cultivation through to sales, by 2028'* (Agriculture Victoria 2018).

These goals will not be achieved if patient access to medicinal cannabis in Victoria (and more broadly Australia) is not opened up.

### 3.5 Issue 5: Public and Practitioner Education and Clinical Practice Guidelines

The public, in general, are not well-informed about cannabis, including the differences between medicinal cannabis and adult use, the different types of medicinal cannabis products, and levels of evidence of efficacy. One of the key actions for the government identified in the *Victorian Industry Development Plan- Developing a Medicinal Cannabis Industry in Victoria 2018-2021* is to '*Develop and disseminate clinical guidance and education materials'*.

As stated previously, NIIM and ACNEM, with input from NICM, have led the development of medicinal cannabis training for medical practitioners and allied health practitioners in Australia, developing a two-day course which has received Category 1 Continuing Professional Development (CPD) points from the RACGP. The first course was run in Melbourne in May 2018 (55 attendees) and the second in Sydney in September 2018 (53 attendees). There are also two other medicinal cannabis courses run by individual medical practitioners which have Category 2 RACGP accreditation. Collectively these courses have trained over 200 medical and allied health practitioners.

The issue is that whilst these courses have attracted encouraging numbers, a greater education awareness campaign (for practitioners and the public) is going to be necessary to reach a greater number of healthcare practitioners, as well as educate the public. Potential risk to patients is substantially reduced when quality-assured medicinal cannabis products are prescribed by knowledgeable healthcare practitioners trained in its use compared with patients self-medicating using unregulated sources.

## 4.0 Potential Actions

The following are potential actions which address the key issues set out in Section 3. The preferred first steps are set out in Section 5.0.

**Action Item 1. Legalise 'adult use' of cannabis.**

One possible solution to the lack of patient access and the issue of driving offences would be for Australia to follow Canada in legalising cannabis for 'adult use'. This would quickly solve the access issue and there are potential benefits in terms of lowering the price of medicinal cannabis to the consumer.

All forms of medicinal cannabis could still be regulated by the TGA. Proprietary forms of medicinal cannabis would be regulated by the TGA, via the Australian Register for Therapeutic Goods (as listed, assessed and registered complementary medicines and registered pharmaceutical medicines), thereby assuring quality and safety and in the case of assessed and registered medicines, efficacy. This could also open up the market for 'clean and green' Australian cannabis products.

**Action Item 2. Adopt the Californian model of legalising medicinal cannabis.**

Another option could be to legalize the possession, consumption and cultivation of medicinal cannabis in a similar manner to California. The Californian Senate Bill 94 (SB 94) – Medicinal and Adult Use Cannabis Regulation and Safety Act (MAUCRSA) – makes it legal for adults 21 or older to possess, consume and cultivate cannabis in California (California Government 2018). The California Department of Public Health's 'Let's Talk Cannabis' website states the following:

*'Use of medicinal cannabis is legal if you have a current qualifying physician's recommendation or a valid county-issued medical marijuana identification card. To buy medicinal cannabis, you must be 18 or older and either have current qualifying physician's recommendation, a valid county-issued medical marijuana identification card, or be a Primary Caregiver as defined in Health and Safety Code Section 11362.7(d). You can possess up to eight ounces of dried cannabis and up to six mature or 12 immature*

*cannabis plants, unless the physician's recommendation specifies a higher amount' (California Department of Public Health 2017).*

The Cannabis plant contains the acid forms of THC and CBD, THCA and CBDA respectively (the acid forms are not intoxicating). Allowing patients to be able to grow their own cannabis plants for personal use would allow patients to juice the plant and/or use it in its dried form as appropriate.

These first two options are unlikely to be popular pathways at this point in time, nonetheless they are options that bear serious examination, given the precedent set in other countries.

**Action Item 3. Off-schedule CBD: remove CBD from Schedule 4 of the SUSMP (and in Victoria, the Victorian Poisons List) and regulate proprietary forms of CBD products as complementary medicines via the ARTG. Down-schedule THC-containing products with no more than 30mg/ml THC to Schedule 4 of the SUSMP.**

In the first instance, CBD should be removed from Schedule 4 of the SUSMP, allowing for CBD to be classified as a 'Listed' Permissible Ingredient on the ARTG. CBD could be listed without restriction or a more conservative approach could be taken of applying conditions such as maximum dosage/ concentration or prescribing pathways (eg. 'practitioner-only products' as opposed to over-the-counter). There are also some potential drug-herb interactions associated with CBD, as there are with many herbal medicines. In this respect, there is nothing special about medicinal cannabis. For this reason, CBD products are best prescribed by someone appropriately trained in its use (i.e. as 'practitioner only products'). This could include medical practitioners and qualified herbalists (western herbalists, registered Chinese herbal medicine practitioners).

THC is currently in Schedule 8 of the SUSMP. Medicinal cannabis products containing no more than 30mg/ml of THC could be rescheduled as a Schedule 4 medicine, opening up greater access to medical practitioners. The responsibility remains as for any prescription medicine, that the medical practitioner monitors the patient.

Victoria could lead the way as a test case for the rest of Australia in removing CBD from Schedule 4 of the Victorian Poisons List and rescheduling THC (as described above), since states/territories generally adopt the Schedules and Appendices of the SUSMP. CBD products could be regulated by the TGA as a complementary medicine (listed, assessed or registered). This is a logical solution given the safety profile of CBD and that it is a plant extract.

**Action Item 4. Decriminalise the presence of THC in the body whilst driving by patients holding a prescription for medicinal cannabis product(s) containing THC provided the individual is not impaired. For patients with a prescription for medicinal cannabis, apply 'Standard Impairment Test' during road-side drug-driving testing. For all others, the standard road laws in relation to THC apply.**

State and territory driving laws could be altered to follow, in part, the Canadian model under which it is an offence to drive whilst *impaired* by cannabis (or other drugs), as opposed to Australia's current laws which make it an offence to drive with any detectable level of THC in the body. Whilst in Canada this law applies to all citizens (since Canada has legalised adult use of cannabis), Australian state and territory driving laws could be amended such that in the case of patients with a prescription for a medicinal cannabis product containing THC, it would only be a driving offence if it was established they were impaired. The remaining laws would stand for all other Australian citizens. Unlike alcohol where there is a level of blood alcohol (0.05) that has been chosen as the point over which a person may be charged with drink-driving, there is no particular level of THC above which it is probable that

someone would be impaired. The bioavailability of THC depends on route of administration. It may be still detectable in saliva and urine a week after it has been consumed. How it impacts the person is variable and individual. If Australia or Victoria legalised 'adult use' of cannabis, this would be a necessary change to state and territory driving laws.

Canada has chosen to use a variety of assessments to establish if someone is driving under the influence of drugs including cannabis. These could be adopted by Australian states and territories and applied to individuals who hold a prescription for medicinal cannabis containing THC. The 'Standard Impairment Test' would be applied during roadside drug-driving testing (see https://adf.org.au/insights/roadside-drug-testing/). Canada has a strong public health campaign in relation to drug-driving. This would be a necessary component of the introduction of any change in driving laws.

**Action 5. Develop a system for licensing of healthcare practitioners who are appropriately trained and certified in the safe prescribing of medicinal cannabis.**

A system of licensing of tertiary qualified and appropriately trained healthcare practitioners should be developed. Appropriate healthcare practitioners include medical practitioners, nurses, and Chinese herbal medicine practitioners since these are all professions that are regulated via statutory regulation. A more liberal approach may also include western herbalists who are appropriately qualified (Bachelor degree training).

The licence would give the healthcare practitioner the authority to prescribe medicinal cannabis products. The licence could stipulate the level of THC allowed to be prescribed by a particular category of healthcare practitioner. For example, products containing high amounts of THC may be restricted to medical practitioners, whereas products containing low amounts of THC or pure CBD could be prescribed by registered Chinese herbal medicine practitioners and nurses. This would necessitate changing the current scheduling of THC (currently Schedule 8 of the SUSMP).

This would then make the current Special Access Schemes and Authorised Prescriber Scheme no longer necessary.

**Action Item 6. Further develop education and clinical practice guidelines- capitalise on existing expertise in medicinal cannabis education to further develop practitioner education, develop public education and awareness and develop clinical practice guidelines.**

The Victorian Government could capitalise on existing expertise in medicinal cannabis education in Victoria, rather than replicating it, by partnering with the organisations already conducting the RACGP-accredited medicinal training course. The Victorian government could:

- support an education awareness campaign for practitioners to reach a greater number of healthcare practitioners
- spearhead a public awareness campaign to educate the public about medicinal cannabis, promoting its safe use through trained practitioners
- support the development of clinical practice guidelines

## 5.0 Recommendations: Preferred First Steps to Open Up Patient Access and Ensure Profitability of the Medicinal Cannabis Industry in Victoria and Australia

A cautious and prudent approach is advocated to open up patient access to medicinal cannabis as well as ensure continued growth and development of the medicinal cannabis industry in Victoria and Australia. Victoria could lead the way, thereby ensuring that the goals set out in its *Victorian Industry Development Plan* stay on target.

It is recommended that a more cautious and prudent approach is taken in the first instance, focusing on opening access to CBD products which do not have intoxicant actions, developing a licensing system for appropriately trained healthcare practitioners, altering driving laws so that patient who are prescribed medicinal cannabis products containing THC are not committing an offence by driving *unless* they are impaired, and supporting the development of education including clinical practice guidelines.

### Recommendations

**Action Items 3-6** are the recommended action items at this point in time:

**Action Item 3**. Off-schedule CBD: remove CBD from Schedule 4 of the SUSMP (and in Victoria, the Victorian Poisons List) and regulate proprietary forms of CBD products as complementary medicines via the ARTG. Down-schedule THC-containing products with no more than 30mg/ml THC to Schedule 4 of the SUSMP.

**Action Item 4.** Decriminalise the presence of THC in the body whilst driving by patients holding a prescription for medicinal cannabis product(s) containing THC provided the individual is not impaired. For patients with a prescription for medicinal cannabis, apply 'Standard Impairment Test' during road-side drug-driving testing. For all others, the standard road laws in relation to THC apply.

**Action 5.** Develop a system for licensing of healthcare practitioners who are appropriately trained and certified in the safe prescribing of medicinal cannabis

**Action Item 6.** Further develop education and clinical practice guidelines- capitalise on existing expertise in medicinal cannabis education to further develop practitioner education, develop public education and awareness and develop clinical practice guidelines.

## Endorsements

These issues have been considered by the following stakeholder groups which have endorsed these recommended action items:

[REMOVED TO ALLOW PUBLICATION PARLIAMENTARY INQUIRY INTO CANNABIS INDUSTRY]

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