Submission to WA Senate Hearing on Cannabis.

05/01/2022

I am a Fellow of the Royal Australian College of General Practitioners and an experienced Cannabis prescriber, with an active role in the medicinal cannabis industry. I would prefer to remain anonymous.

Please find a brief outline of the issues I have encountered in the Medicinal Cannabis space of WA below.

An overview of the typical Cannabis patient, to provide some context.

Currently, Medicinal Cannabis can only be prescribed to patients with a chronic symptom (suffered for greater than six months), who have tried and failed a reasonable number of conventional treatments. Therefore, almost by definition, patients that are prescribed Medicinal Cannabis tend to be the oldest, sickest, frailest and/or the most treatment-resistant cohort.

These are patients that are in great need of symptomatic relief, as little else that has been offered them has proved useful. Note that there is an ever expanding list of conditions and symptoms that have at least some evidence supporting a trial of medicinal cannabis. A non-exhaustive list includes; ADHD, ASD, anxiety, chronic pain, cancer symptoms, chemotherapy symptoms, nausea, depression, tremor, neurodegenerative disease, palliative care, wasting, muscle spasm, insomnia, seizures, inflammatory arthritis, inflammatory bowel disease, irritable bowel and PTSD.

Note that patients that are burdened with chronic disease invariably have multiple pathologies, and multiple symptoms that might be amenable to Cannabis treatment.

Also note that patients that suffer from chronic symptoms invariably also suffer from financial stress. This is due to the costs of their health care as well as loss of income. It is through this lens that Cannabis Medicine must be viewed; our patients are in great need.

Driving.

The issue with Cannabis medicine and the driving laws are not unique to WA. However the rules here are discriminatory towards patients that have been prescribed Cannabis; If any THC is detectable in a driver's samples it is illegal to drive. This includes roadside mouth swabs, and blood serum testing.If a mouth swab is failed, or if the driver is in a crash, then the police may proceed to blood testing.

In serum testing for THC, minute levels can be detected. THC may remain present in the serum at these low levels for weeks or months after a patient has last taken a dose of cannabis. Cannabis is detectable at a level well below that of intoxication. There may be legal

consequences for someone even weeks after consumption, even if legally prescribed by a doctor, and even if not remotely intoxicated.

This obviously presents a major barrier to treating patients with any form of cannabis medicine. Most patients would not like to risk being in breach of the law, despite their clinical need for the treatment. There is no published information as to the cut-off thresholds of police serum or saliva testing that I know of.

There is of course enormous variability from patient to patient as to the sensitivity to THC, and therefore the serum levels that cause intoxication, as well as the metabolic rate, which determines the length of time the patient requires after dosing to clear all traces of THC from their samples. There is no current legal defence against the drug driving laws, including having a current, valid, legal prescription.

WAPOL must consider sobriety testing for cannabis patients, to determine if patients are impaired in terms of driving whilst taking THC containing products.

Note that many cannabis products contain only trace, or low amounts of THC, and are therefore not considered intoxicating. Over time the low levels of THC in these products can build up to detectable levels in the serum, due to accumulation of THC in the person's body fat. Therefore patients that have never consumed an intoxicating medicine, and have never had their driving impaired, are discriminated against in the current legislation as much as an active illicit cannabis user.

Also please note that I have heard many anecdotal accounts of illicit users having recently consumed THC prior to police mouth swab testing, and not been flagged. This implies that the testing regime as it stands doesn't actually detect the very people it sets out to deter.

Additionally, I have heard anecdotally that some police officers will waive the mouth swab if a patient states that they have a prescription for medicinal cannabis. This to me implies that there is an unofficial policy in place in some traffic departments already. I would appreciate some clarity on this, and ideally a firm commitment from WAPOL to avoid stigmatising and discriminating against medicinal cannabis users.

FIFO site testing.

Mine Site and other workplace drug testing suffers from much of the same issues as the situation in regards to driving.

Firstly, as the State determines that any detectable THC in the system makes a patient unfit to drive on the road, most HR policies follow this by claiming that detection of THC makes an employee unfit to operate machinery, work underground/at height/at sea, or to drive on site.

Again this is despite the fact that THC simply being detectable in the saliva, serum or urine does not confirm that the person is intoxicated, impaired or cognitively affected.

Most of my working age patients that seek Medicinal Cannabis treatment suffer from sleep disturbance, this is often especially severe in shift workers. THC almost universally seems to improve sleep in this cohort. Patients in this situation self-report feeling more alert and less impaired after their sleep has improved, or if they are able to cease other sleeping medications such as benzodiazepines.

There is huge variability in workplace drug testing. Some workplaces have a zero tolerance policy. Some undertake morning mouth swabs only, which are less sensitive and unlikely to detect use from more that 4 hours ago. Some workplaces will allow a THC positive result in the urine, as long as there is a doctor's letter.

I think it would be extremely beneficial to the workforce of WA if there could be mandated consistency in the drug detection approach by employers, again avoiding undue stigmatising of Cannabis patients, and descrimination of patients who use Cannabis over other intoxicating sedatives.

Max dosing.

The WA state DoH has set a blanket maximum THC dosage from GPs at 30mg per day. With specialist support the maximum allowed dosage has been set at 60mg per day.

It is unclear what evidence this decision has been based on. I have contacted the Medicines and Poisons Branch (MPRB), and they have been unable to furnish me with papers that they have used for guidance on this matter.

The universally accepted clinical guidelines for oral THC dosing is one of starting low, and titrating up slowly to an effective dose: generally starting at 1 - 3 mg per day and increasing every 1 - 5 days, by 1 - 3 mg increments, until the lowest effective dose has been found.

A large proportion of patients require dosages above 30mg. Some require dosages above 60mg per day. As mentioned above in my discussion regarding driving, there is very broad patient to patient variability in terms of Cannabis metabolism, but also in terms of response and sensitivity.

If the patient is told to titrate gradually to the lowest effective dose or the government mandated maximum dosing - whichever comes first - then this is not going to provide adequate symptomatic relief to a proportion of the population of patients.

I have been told by an MPRB doctor that the dosage caps have been imposed to minimise side effects that patients experience. In my experience the absolute dosage the patient uses has little bearing on the side effects that they experience - rather it is the rate of titration and hence the development of tolerance to the side effects which is of highest importance. There are many

other tips and tricks that can be discussed, on clinical review, which can be utilised to improve the balance of side effects to response. In other words, side effect management is clearly a purely clinical issue best approached by the treating doctor and not by the blunt instrument of sweeping dosage caps.

THC consumed orally is rapidly metabolised into 11-hydroxy-THC, an active metabolite that actually has a higher psychoactivity than THC itself. THC consumed by inhalation does not exhibit a rapid conversion to 11-hydroxy-THC, as such there is actually less psychoactivity from vaporised cannabis, milligram to milligram, as compared to oral preparations.

Despite this well known difference in metabolism between the two administration methods, alongside a multitude of other differences in absorption and profiles, the WA DoH places the same daily THC dosage cap on inhaled products as oral products.

Most inhalational products prescribed are in dried whole flower form. These are labelled by strength in % THC by weight. Most flower products are between 10 and 30% THC.

This means that the MPRB allows prescribing of up to 0.3 grams of 10% flower or 0.1 grams of 30% flower per day. To put this in context, 0.1g is equivalent to around 5 grains of dried rice. Kitchen scales are generally accurate to 1 gram.

There are therefore very few patients that can accurately adhere to such dosing mandates. 0.3 grams can be lost very easily; being dropped, blown away, burnt and a host of other every-day accidents. One ten gram container of 20% THC Dried flower is expected to last a patient 67 days. The restrictions on dosages prescribed means that prescription of dried flower is essentially impractical.

Please note that dried cannabis flower by vaporisation is an extremely effective and versatile administration method and, in my experience, is easy to titrate, easy to tolerate in terms of side effects, and highly valued as a PRN symptom reliever by many patients, including the elderly.

A further point regarding the max dosing mandated by the State; I have heard from multiple sources that not all doctors are treated equally. Some GP staffed clinics have been allowed to prescribe up to 60mg/day without written specialist approval. Some specialists have been approved to prescribe over 60mg/day. Some independant GPs have been approved for higher doses without specialist approval. I would like to request some clarity on these discrepancies.

Note the excellent safety profile of cannabis products. There have been no recorded overdose deaths, in contrast to many conventional medications.

I suggest that the MPRB is not required at all in the approval process. Queensland's DoH has no involvement. NSW and Vic DoH understandably have other issues occupying their Public Health Department. There have been no issues with over-dosing in those states.

Remember that all prescriptions have been approved by the federal TGA prior to the 'assessment' by WA MPRB - either via the SAS-B or the AP pathways. The MPRB is doubling up on work. The TGA never mandates a maximum dose to the practitioners, it always leaves dosing to the discretion of the treating practitioner.

Requirement for specialist approval.

GPs can currently prescribe up to 30mg THC per day without specialist approval. However, to prescribe higher doses, or to prescribe to patients that are registered as drug dependent or under 18 years of age, specialist approval has to be included in the application.

While I appreciate that the State DoH wants to add a layer of assurance that the prescribing is appropriate, unfortunately this approach is unfair and impractical.

Firstly, one could argue that there are no or very few Specialist Consultants more informed or more experienced in Cannabis Medicine than the General Practitioners like myself, who see many Cannabis patients per day. Whilst we may not have the advanced and detailed knowledge of the specific conditions that we treat, we have the knowledge and experience in Cannabis based medicines that is lacking in specialist training and exposure.

Remember that Cannabis is a symptomatic treatment, and not generally considered curative. One must have an understanding of Cannabinoid pharmacology, drug-drug interactions and, most importantly, have excellent skills in assessing the nature of the symptoms and their impact on the patients life and well being. The minutiae of the pathology is not necessarily required. More important is having the time and understanding to explain the subtleties of cannabinoid treatment approaches.

GPs are best placed to become the recognised experts in Cannabinoid medicine. This is because GPs are comfortable managing all age groups from birth (even antenatal) to death, and all complaints from simple situational stressors to genetic multisystem syndromes. GPs are able to follow a patient from beginning to end of their disease. Due to the ubiquitous presence of the endocannabinoid system throughout essentially all processes of the body, Cannabinoid medicine is *potentially* applicable in all medical and psychiatric conditions. It is certainly applicable in a vast array of documented conditions. Specialists are highly unlikely to treat conditions and symptoms outside of their focus. Most patients with chronic disease have a range of comorbidities and disparate symptoms. Often these issues are linked by endocannabinoid dysfunction. The experienced Cannabinoid doctor can often provide relief to a host of symptoms with a single agent.

With the current arrangement, patients requiring Cannabis treatment are often forced to seek a specialist opinion. There is essentially no engagement with Cannabinoid treatments at our local tertiary public hospitals. Patients must go to private specialists, pay hefty fees, and have no guarantee that they will be approved for treatment. The majority of patients with severe chronic

disease are also financially stressed. There is essentially a two-tier system; those that can afford to pay to see one or more specialists, and those that can't. This is clearly unfair.

I suggest that, on submission of proof of an appropriate level of accredited training, experienced Cannabis prescribing GPs should be treated as de facto specialists by the MPRB, with the level of recognition, respect and trust appropriate.

Specialist approval for drug dependent persons.

There is a clear discrimination against patients that have been labelled drug dependant. These patients are not able to be prescribed THC without Specialist approval. It is expected that an addiction medicine specialist approve their applications. However, there is no private route for seeing an addiction medicine specialist. The public system consultants seem to have no desire to stand up to the bureaucrats of the MPRB. If an addiction specialist can be found to approve the applications, their written support may not be deemed adequate for the MPRB to sign off on the prescription. They seem to also demand the approval of a second specialist they feel is relevant to the symptom (usually just one picked out of many applicable chronic symptoms) that has been named as the primary indication on the application. The goal posts keep moving.

Note that Cannabis medicine use tends to be associated with a reduction in requirement of opiates and benzodiazepines.

Specialist approval for >2 products.

Should a GP deem it in the patient's best interest to prescribe three schedule 8 Cannabis products, the MPRB seems to feel that a specialist approval is also required. A common scenario is that a patient might be prescribed low THC: high CBD oil for mornings, high THC: low CBD oil for night, and a flower preparation for as-required use, should symptoms be exacerbated. However, the MPRB seem to feel that this simple combination is outside of the expertise of a GP. The rationale provided was that three preparations constitute polypharmacy, and this is deemed too high risk.

One could argue that actually the three prescriptions in question are actually just different preparations of the same active ingredients. It is certainly not a difficult group of preparations to manage. The MPRB is at risk of forcing patients into taking high THC: low CBD day and night, rather than saving for the evening; this is more likely to introduce side effects.

Of course, as mentioned above, patients tend to wean off of opiates, neuropathic treatments (pregabalin, amitriptyline) and sedatives, amongst other symptomatic treatments, with the introduction of Cannabinoid treatments. Limiting the use of Cannabis products arbitrarily will result in more polypharmacy, as more of these medications will be retained to achieve desired results.

Summary of impression of the role of the MPRB in Cannabis based medicine.

It is my impression, from many interactions with the MPRB, that there is zero real-world experience with Cannabis as a medical treatment within the department. The mandates are restrictive to the point of being obstructive and impractical. There is certainly no evidence cited to support the maximum dose capping, the restriction on the number of concurrent products, and in practical terms, the near ban on Medicinal Cannabis treatment in 'drug dependent persons.' I have requested the evidence used in decision making several times.

As noted, many of the restrictions placed on GP prescribing result in unintended consequences which likely have the opposite effect that the department is looking for. Any input from an experienced prescriber would have illuminated the regulators to these consequences, but the decision making seems bureaucratic and not clinically based - or indeed evidence based.

Note again that there is inconsistency in the approvals that are endorsed or declined, especially from doctor to doctor with some obvious preferential treatment from the MPRB to certain prescribers, but also from patient to patient. It seems to depend on which delegate has assessed the paperwork. All approvals that are declined are signed by an anonymous 'Delegate to the CEO'. There is very little transparency.

It is my impression that efforts of the Cannabis branch of the MPRB seems to be just 'busywork'. Again, noting that the TGA has already performed it's role as regulator of unregistered products, I suggest that the MPRB involvement in Cannabis prescribing is scrapped with efforts diverted to more needy areas of public health; the pandemic, contact tracing and vaccination.

Onerous paperwork.

Needless to say, there is an enormous amount of paperwork required from a Cannabis prescribing doctor. This is obviously obstructive to the process of providing required treatment to needy patients. The doctor almost always must pass on the cost of this paperwork to the patient in the form of private fees, in order to make treatment viable. Streamlining of the process will reduce costs to the patient.

With SAS-B applications, the TGA requires submission of anonymised details outlining the appropriateness of the use of Cannabis, as an unregistered medication, in that particular patient. This system is clearly under regular scrutiny and efforts are regularly made to streamline and improve the process.

An experienced prescribing doctor can apply to the TGA to be listed as an Authorised Prescriber (AP), and again this process is regularly updated and streamlined. The TGA is efficient and reasonable, and few doctors have any qualms with the federal parts of the application processes.

On the TGA website portal, WA DoH has added it's own page of required information, some of which is duplicating the TGA's questions. There is a requirement for uploading files, which must only contain a duplication of the information the TGA requires, but in a more time consuming format.

Once an application has been submitted, the prescriber must await an emailed authorisation certificate. The TGA portion of the authorisation process takes minutes to hours. The WA portion takes several days to arrive.

When an AP prescribes S8 cannabis products to a patient in WA, they must submit a 'notification form.' This is quite a time consuming form, especially if one submits many forms per day. Then the MPRB will reply to the practitioner via posted correspondence. Although labelled a 'notification' form the MPRB may reply declining authority, thereby making the form an application rather than a notification. Often the MPRB will request, again by post, further information regarding the application. This request is often something simple, like a copy of the TGA authority paperwork. Very often the paperwork requested has already been sent to the TGA on numerous occasions.

It is clear that the MPRB cannot keep up with the paperwork submitted by prescribers, as there are often declinations of AP notifications, based on outdated information. This requires us to resubmit the forms again, and include paperwork and extra documentation that has already been submitted numerous times.

One example is a patient of mine that has previously been labelled drug dependent, but has a letter from their psychiatrist explaining that this is no longer the case. With each application on this patient's behalf, there is a back and forth with the department requiring resubmission of the psychiatrist's letter and further time consuming justification of the clinical decision making process. Remember that the department corresponds via post only, making such a process very lengthy.

Clearly the MPRB cannot maintain the files they have on prescribed patients. Streamlining of the paperwork - I suggest abolishing the notification process - will make prescribing simpler for prescribers, cheaper and quicker for patients, and reduce State government workload. Note that month on month, Cannabis prescribing rates are increasing.

It is unclear why the MPRB does insist on notification forms for each product each patient is prescribed. From my knowledge the form itself there is zero useful public health data to be gleaned. Additionally there really seems to be no obvious way that these forms improve patient safety. Considering the TGA are responsible for the safety of registered and unregistered medications, there is certainly a doubling up of work. If there was a clear aim that the MPRB has in mind I suggest they consult with local prescribers, as we could suggest means to better assess the data or better manage the safety concerns.

Note that if the paperwork burden was reduced there would be an increase in the number of local (and time poor) GP prescribers, as barriers decrease. More patients would be able to access Cannabis medicine from their own GPs, or at least within their own practice, instead of having to seek other prescribers.

Regulations in other states.

Schedule 8 medications come under the remit of the State, rather than federal legislation. In NSW and Victoria there was previously a requirement for prescribers to notify the State public health departments about Cannabis prescribing, but this has been lifted now, as the current public health issues surrounding the Covid-19 pandemic rightly take precedence. Now the DoH must be notified only if an under 18 or a drug dependent person has been prescribed S8 Cannabis products. However this is a true notification, not an application.

Queensland requires no notification of Cannabis prescribing to the state. The federal TGA is entrusted with providing medication safety oversight.

In Tasmania, the driving laws have switched from pursuing detection of THC, to assessing for driving impairment. Therefore there is no descrimination of legally prescribed Medicinal Cannabis patients by the traffic police.

Interstate access.

With all of the barriers outlined, many patients are becoming aware of an obvious alternative route to accessing Medicinal Cannabis Products; inter-state prescribers. It is an easy step for patients to search online for telehealth clinics based over east and self refer for treatment. These prescribers will make their assessment over the phone, and prescribe as they see fit, and have the products posted to the patient across state lines. This is completely legal. There is no reason for the prescribers to adhere to the restrictive legislation of the WA DoH as the medication is dispensed under a different jurisdiction.

The main argument about seeking parity with other State regulators is one of safety. Patients are forced to access telehealth only clinics interstate, splintering their care from their GPs. Arguably, telehealth reviews can never be as comprehensive and holistic as a face to face consult. There is greater difficulty in seeking the follow up of the prescriber, should issues arise. There is a higher risk of elements of patient care ‘falling through the gaps.’

There is an obvious financial argument also. If a WA based patient seeks prescribing from an interstate telehealth doctor, the local medical practices miss out on revenue, as do the local importers, distributors, pharmacists and a host of other supporting staff.

Thank you for taking time to read my complaints and suggestions, regarding medicinal Cannabis regulation and access here in WA. There have been improvements to access in the recent past. Hopefully we can accelerate this trajectory for the benefit of our patients - benefits for our local industry will follow.