Summary of submission from MCUA of Australia Inc.

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Ms Gail Hester,
Executive Committee,
Medical Cannabis Users Assoc of Australia (MCUA) Inc

To: Community Affairs Reference Committee,
Australian Parliament, Canberra

5th January 2020

RE: **Current barriers to patient access to medicinal cannabis in Australia**

Thank you for the opportunity to make a submission to this important Inquiry. I am the founding member of the Medical Cannabis Users Association (MCUA) of Australia Inc. and I am writing on behalf of our 18,500 members.

MCUA was created in 2014 as a social media group for Australians who wanted access to cannabis for medicinal use. In 2015 the MCUA became an incorporated, not-for-profit patient based association which interacts with patients **every day.** We have worked closely together lobbying at grass roots level for access to cannabis for medicinal use.

In 2016 patients were granted heavily regulated access to costly imported "cannabis based products". Access was slow and laborious with only a handful of patients gaining bureaucratic approval in the first 2 years.

In January 2018 when Federal Health Minister, Greg Hunt announced export licences would be available, and while the government built an export industry aimed at "world domination" he assured us that "***one of the conditions of any licence for export is that medicinal cannabis be made available to Australian patients first***"

This has NOT been the case.

Now almost 4 years since changes to the Narcotics Act, there are still NO Australian grown and manufactured products regularly or readily available to Australian patients at affordable prices. Our Mission now, has become working *toward the establishment of a fair, sustainable, affordable and acceptable Cannabis access model that is patient centred and herbal based.*

There are several ways this can be achieved and international models that could provide a basis for a more suitable delivery model. Now that the export industry has been established, it is time to focus on patient needs.

We note that prior to the vote on this inquiry, the LNP made its position clear when Senator Duniam said: "the government **does not support the premise of this proposed inquiry.**"

Political bias was the reason the MCUA started a petition prior to the announcement of this Inquiry, asking for the **Australian Advisory Council on the Medicinal Use of Cannabis** (AACMC) to review the current delivery system with the view creating a fairer, more affordable delivery model in consultation with the end users. That petition became redundant but comments will be included from the 5,000 people who signed it.

In conjunction with the petition, the MCUA undertook a **Patient Satisfaction Survey** of those who have been through the current approval process. We had over 200 respondents. Data was constant and consistent throughout the collection phase. On closing the survey, data showed that:

◆ 86% of patients were somewhat (16%) or **very dissatisfied** (69 %) with the ease of access, adequacy & affordability.

◆ Just under 45% said they got approval but were unable to fill the script because of cost.

◆ 63% said their only income was Centrelink payments.

◆ 66% had to go a clinic because they couldn't get GP. to do it under Medicare.

◆ Application and consultations fees at these clinics ranged from less than $100 to over $1000. Only 28 % got a rebate. Around 10 % were told about compassionate access from the product sponsors.

◆ To date only around **25,000 approvals** have been granted. This does not equate to actual patient numbers accessing legal products. The **average from our survey has been around 3 approvals per patien**t, some having as many as 10 approvals.

◆ Many of the prescriptions written have not been filled. Some approvals were for more than one product for the same patient and some are for product changes. This reduces **patient numbers to around 7,000** in 3 yrs, while the black market and personal cultivation has serviced 100s of 1000s of sick, suffering, disabled and socially disadvantaged Australians who are unable to get access to affordable legal products.

It is from that survey and patient feedback though our group that I will be addressing the following points in the terms of reference on behalf of patients in the MCUA:

(a) the appropriateness of the current regulatory regime through the TGA SAS Authorised Prescriber Scheme and clinical trials;

(b) the suitability of the PBS for subsidising patient access to medical cannabis products;

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

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

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

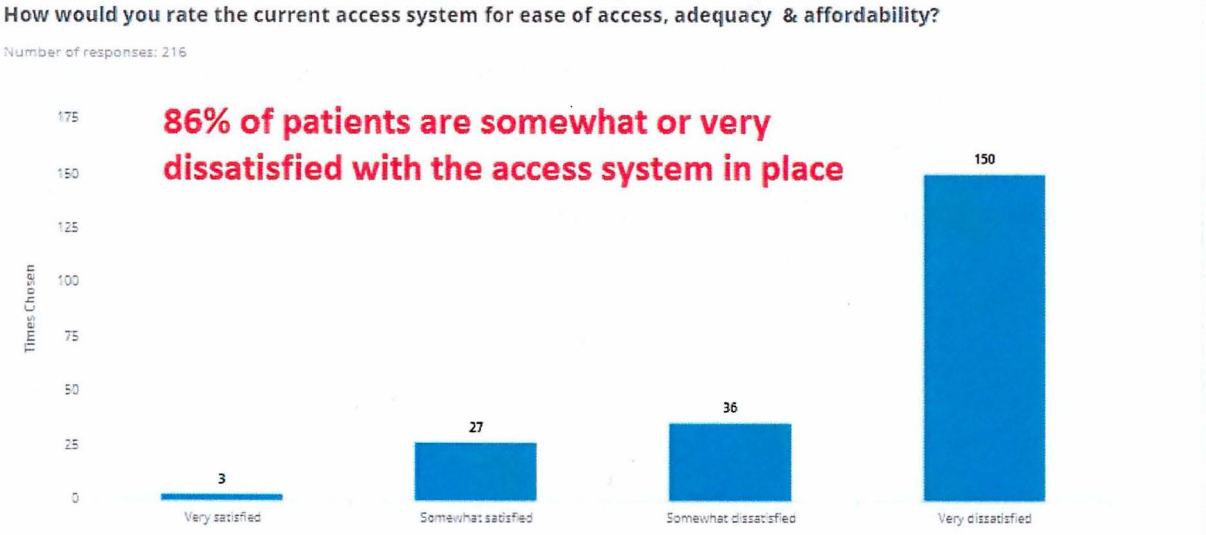
(l) the significant financial barriers to accessing medicinal cannabis treatment

(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.**

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

Cannabis is not a new drug. It is a herbal remedy that has been used throughout history with no recorded deaths. It should be treated as a botanical substance rather than tying it up so tightly in pharmaceutical red tape that prevents patient access.

The general consensus from the patient feed back is that the current **regulatory regime** is not working for MOST of them due mainly to significant financial barriers to access and products.



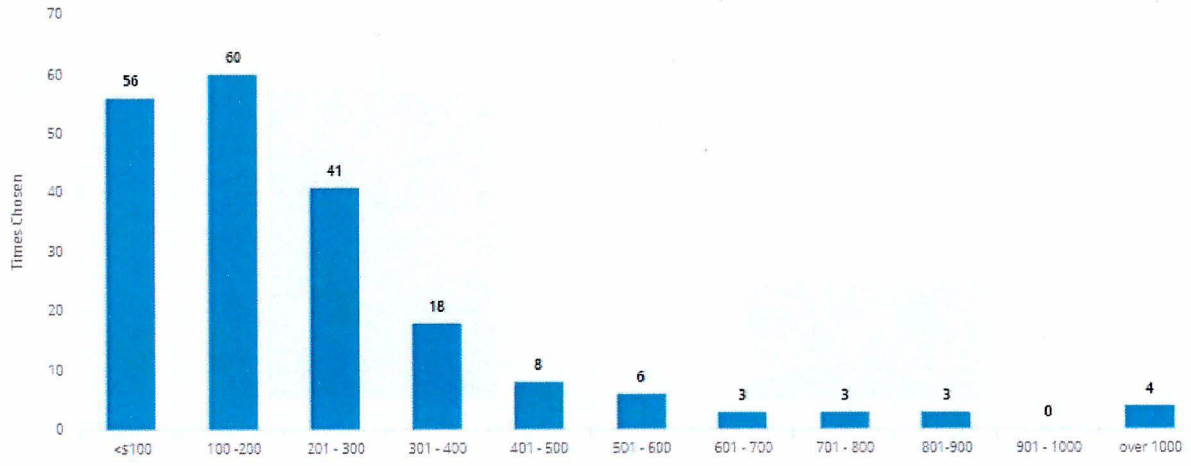
1. **Authorised prescribers** are like the proverbial "hens teeth" and in the early days of legal cannabis, many of our members tried to get the name of one, but it became Australia's best kept secret. With the take over by corporate clinics the need to know has been reduced.

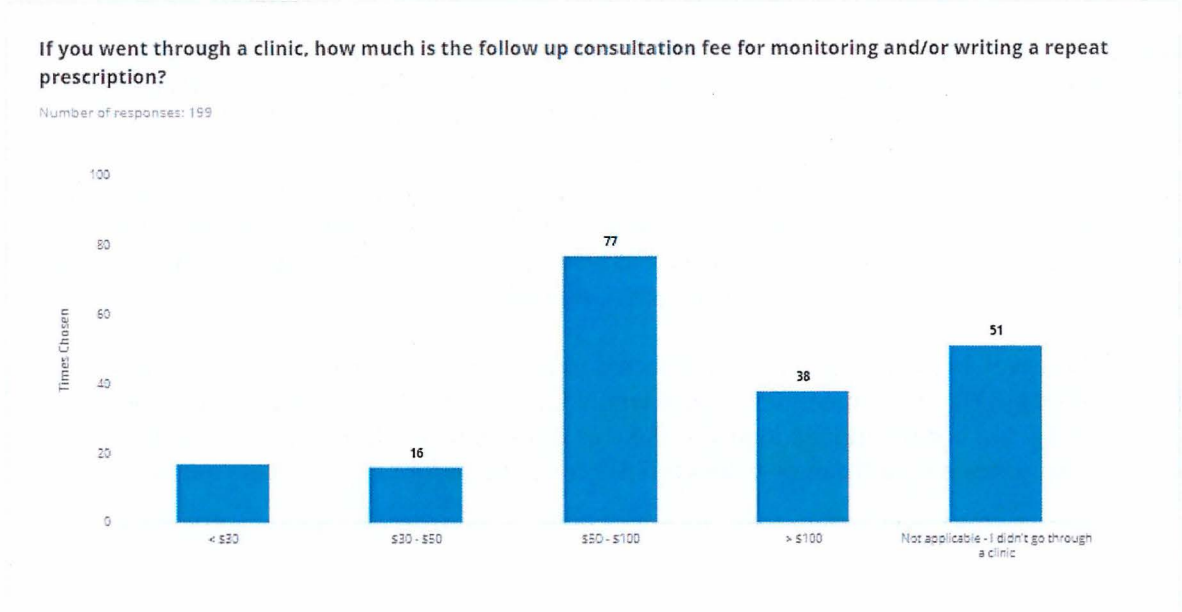
2. I have not heard of one of our 18,500 members being accepted onto an official **clinical trial**. We have several who say they have been on product based trial for manufacturers (company use of research and development licenses). Products that were given to them at a slightly reduced price during the trial period, reverted to their listed price when the "trial" was over.

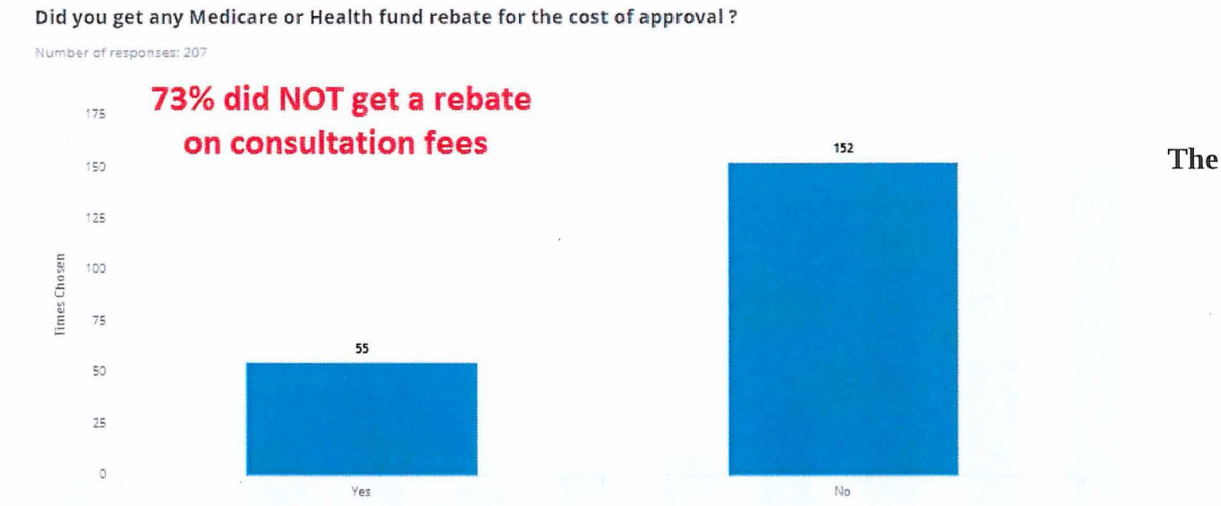
3. **Special Access Scheme** prescription-only-access to unregistered products has been the only option for the majority of our members. Those who's GP or Specialist refused to prescribe have often had to beg and borrow money to afford the cost of **corporate clinics fees** for the assessment and application process which can cost between $250 – $400 before any products are purchased.

How much approximately did the consultations for the initial approval process cost ? (excluding follow up consultations)

Number of responses: 202







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Prescription ONLY pharmaceutical model has been by far the biggest barrier to access.

This model was thrust onto doctors without consultation or an Inquiry into the best options and has created doctor reluctance that became a substantial contributing barrier to patient access for many reasons:

(i) Without any warning or training, doctors suddenly found themselves as the "gate keepers" to a drug that many had been telling patients for decades was dangerous, addictive, illegal and caused mental health issues. Concerns were raised about being known as the Pot Doctor and

being inundated with "pot smoking hippies". This is still the case. Our MCUA President had this experience just recently when asking for a prescription.

(ii) The time consuming application process gave rise to further reluctance. Over worked GPs (and Specialists) didn't have the time or knowledge to take it on and as we saw in MCUA's patient survey from 2016, they made excuses ranging from "I don't know enough about it" to "Its illegal" and "not enough evidence" were commonly being used.

(iii) As seen on the NSW Centre for Medicinal Cannabis Research and Innovation website until it was removed from the FAQ section in 2018, is another reason for this reluctance:

Why are some doctors ***reluctant to prescribe*** *a cannabis medicine?*
Any doctor who prescribes an unregistered cannabis medicine to a patient also assumes legal liability for that patient's welfare. *A doctor running a clinical trial will be covered by the hospital's medical indemnity insurance; a doctor prescribing a cannabis medicine to a single patient will assume liability personally.*

*(*Not sure if this is the case with ONLY cannabis or with all unregistered medicines - have been **unable** to find out).

One can hardly blame them for their disinclination to prescribe. And for these reasons, patients are being denied access.

Without customers and doctor support, the fledgling cannabis industry floundered for many months with very low approval rates and imported products languishing on warehouse shelves until the birth of Corporate Cannabis Clinics. These are the brain child of international corporations seeking profits for hungry shareholders and they became the new gateway to moving products here in Australia.

According to ***David Radford - CEO of global cannabis company THC:*** **"**these clinics are not subjected to the regulatory hurdles of a usual health clinic." (one can only wonder what that means)

These clinics began popping up like mushrooms after a storm. They are staffed by part time doctors, mostly with no prior experience in a clinical setting that uses cannabis medicine yet they are employed to assess the suitability of patients for a "trial" of cannabinoid therapy; prescribe cannabis; monitor the treatment in conjunction with a patient's GP. More importantly their job is to interface with regulatory bodies as required. Many of the consults are done by via teleconsults. Experience in treating patients with cannabis "is a plus" but not an essential in their job advertisements. These clinics are charging fees to put in an application to the TGA that attracts no fee. They are charging "Specialist" consultation rates and monitoring fees for which patients can rarely get a Medicare or Health Fund rebate.

These clinics are not in the best interests of patients when we see comments like this by a patient with a very complex suite of conditions who contacted me:

"… the doctor never looked at the paperwork I brought with me (medical records) and did not even ask if I had any allergies. He didn't ask if I had mental illness in my family. He didn't ask any questions one would think a doctor would ask before prescribing a new drug… The doctor I saw simply told me he was getting my approval done asap. Was more interested in getting my $$$ and onto the next patient. There would have been 20 people in the waiting room for this one Dr."

The prohibitive cost of imported products has been the other big contributing barrier to access for the majority of patients. Even though sponsors of imported legal products have a "compassionate supply" option available none of our members have been granted compassionate access by sponsors to date.

SMALL SELECTION OF PATIENT FEEDBACK RE THE SYSTEM:

….. I'm a DVA pensioner and they will pay for the oil if I can get a 'Pain specialist' to say I need it, my GP, Shrink and the Dr who gave me the script are not sufficient for them. So I have the script and have to find a pro cannabis 'Pain specialist' because I'm broke ...

…. I recently applied for the legal version, knowing fully well it was way outside what I can afford. It cost me $200 for my initial appointment, $59 for any subsequent scripts, $80 follow up appt, $59 whenever I have to adjust dose or product, which I was able to afford by making a debt with centrelink, I got TGA approval for 2 different products. One is $660 a month, one is $300 a month. Needless to say, I cannot fill in these scripts….

… What they are NOT telling you is the cost. I tried going through one of these clinics and the approval cost was around $1500, BEFORE anything is dispensed. Then the cost of the oil is NOT subsidised **…**

… I have just been approved, and I get 25 ml of 25% CBD and THC. You have to order two at first. These clinics are expensive and charge about $300 for the initial consultation. It's all a money making venture for many. Even for those like myself that desperately need it, it is way out of the affordability to sustain. Mine is $420 for 25 ml. They make you buy two at first. ***The second one is still sitting at the pharmacy, but I cannot afford to pick it up ...***

…. I am lucky in that my partner earns good money but we had to decrease our rent by 200 bucks (smaller house dodgier area) to make it work. ….. every order has been left at the door and I live in a unit complex in a dodgy area. My last order was $1290 for 2 months supply. ***It really will be last order, I've been on it almost a year now and cant afford it any more.*** *All the fuss and rules to obtain it and yet its totally ok for them to leave at the door, I do not understand. Oh and there was that time it got sent to the wrong address...*

… total cost for consultation and application fees was $120. The products were quoted at $385 per bottle and I would have to purchase two bottles at a time. I currently work a total of 12 hours per week and have been seeking access to the Disability Support Pension for 6 years now. I make less than $1,000 a month and as I quickly went up with the dosage it became clear that I would require one bottle every 5 days. This would lead my treatment by CBD to cost well over $4,000 per month. In order to pay for the first dose ***I had to borrow money from my mother. a situation which was more disappointing because the oil did not work….***

… My GP was happy to send me. (to a clinic) I called and the Consultation alone was more than my weekly income (after rent). The referral is still sitting on my desk. Its far to expensive for me to even consult with one of these clinics let alone get a script filled. Seems its only for the rich whilst the less fortunate have to suffer...

… My first appointment was $300 and I need a review at $60 for a new prescription I'm on Althea Champlain thc 21% 100ml That was $300 And the other one is cda clinics CBD 240 oil 2400mg 10ml at $275. The CBD oil lasted me about 3 weeks, I have job for now, but there is going to be a point when I can't, which I don't know what will happen...

I have also heard stories from patients about a couple doctors stepping outside the legal framework and treating patients with cannabis preparations other than those approved by the ODC.

… She was at xxx. Dr xxxx. *I made an appt. and when I was seen I asked if she was able to help me find some oil. Showed her my 'diagnosis' of the cancer and she said she had oil she could sell. It was $100 which I paid by cash and she put the $ in her pocket and gave me a bottle of the oil and I left in hope Just bought the oil, no other offers of help or scripts etc I didn't ask for a script, she*

didn't offer. I was just grateful to have the oil. It did nothing so I just a couple of drops a day as a tonic ….

….. They have been very helpful to me. That being said though, I just want to make sure I'm not being naive and that I have tried to do some kind of research to determine that the oils sold via OneBody Foundation are quality medicine. I was originally connected with a dude named Terry H Clarke (clearly a pseudonym) after reading this article and contacting the administrator. *https://eternalplants.com.au/rick-simpson-oil/where-to-buy-rick-simpson-oil-online/*

Terry and I then had many emails back and forth and he provided a great sea of excellent information without pressure for sale. He provided advice on which blend he felt would be best suited to my cancer, however he felt it was important to have his recommendations doublechecked by a cannabis doctor, and that is when he referred me to Dr XX.

My understanding is that this doctor does apply for TGA approval, for those who fall within conditions that would apply for medication is covered by the TGA. For those of us who are seeking treatment outside that framework he will link you up with the supplier on the covert down low He can help patients access through TGA as well .. I had no prescription as such. (The doctor) sent me a summary of dosage advise and direction around which blend would be best to purchase. I then contacted supplier who gave me this link and indicated the green bottles were the full spectrum blends. I am on the 180. http://www.onebodyoils.me *where it states that"**100% of profits from our site go to support our humanitarian team in Nepal, providing solar projects, community development programs and education sponsorships."***

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

In many US jurisdictions where cannabis is legal for medicinal use, doctors "recommend" rather than "prescribe" cannabis. Patients are then sent to a dispensary where they can purchase products and plants. "..Like the grocery store, you can select your products according to your needs but if you need assistance, staff are more than happy to share the breadth of customer feedback they have received about different products..." They suggest strains, doses and administration methods that range from buds for vaping to oils and tinctures, balms, suppositories and edibles – a host of products that are NOT available to patients in Australia unless they are accessing via the black market or self supplying by home grow. https://www.shopharborside.com/faq/
Prices are considerably cheaper than we are paying
https://harborsidesanjose.treez.io/onlinemenu/category/tincture

A similar system exists in Canada where patients can purchase products directly from the manufacturer. In both these models patients are issued with a medical cannabis card on recommendation from a doctor.

In Canada you meet with your health care practitioner to discuss whether you should use cannabis to treat your symptoms. Your health care practitioner may provide you with a medical document if they determine that cannabis should be used to treat your symptoms. You can register with a licensed producer to obtain cannabis products for your own medical use, including: fresh marijuana, dried marijuana and cannabis oil. To register with a licensed producer of your choice, you will need to complete a registration form specific to that licensed producer and provide your original medical document
https://www.canada.ca/en/health-canada/services/getting-cannabis-from-licensed-producer/accessing-from-licensed-producer.html

Here in Australia we currently have at least 5 illegal dispensaries regularly servicing about 15,000 patients and several compassionate suppliers/cannabis clubs who service many hundreds more between them with whole plant products. Some monitor patient progress via record keeping; others consult, advise and supply products. Some charge a small consultation fee- most dont. Illegal dispensaries also offer compassionate access and care packages to those who are unable to pay.

There are also innumerable people who grow for themselves and help others while doing so. Success rates - anecdotally speaking, have been very high – especially with epilepsy, PTSD depression, anxiety and chronic pain. On top of this there are numerous CBD online sellers who continue to defy the rules and hundreds of patients who are more than willing to use these services.

A good number of these illegal suppliers / healers / carers have been raided and prosecuted. Many have been "smacked on the wrist" by the courts in recent times, but are back at it as soon as court is over. There is an absolute wealth of knowledge and experience in these suppliers – many of whom have been "treating" patients with whole plant herbal extracts for years and most users would trust them before they would trust a registered untrained doctor to supervise and advise them on treatment.
The dispensary system similar to the one used in the US along with home grow is very much what many patients would like to see here in Australia.

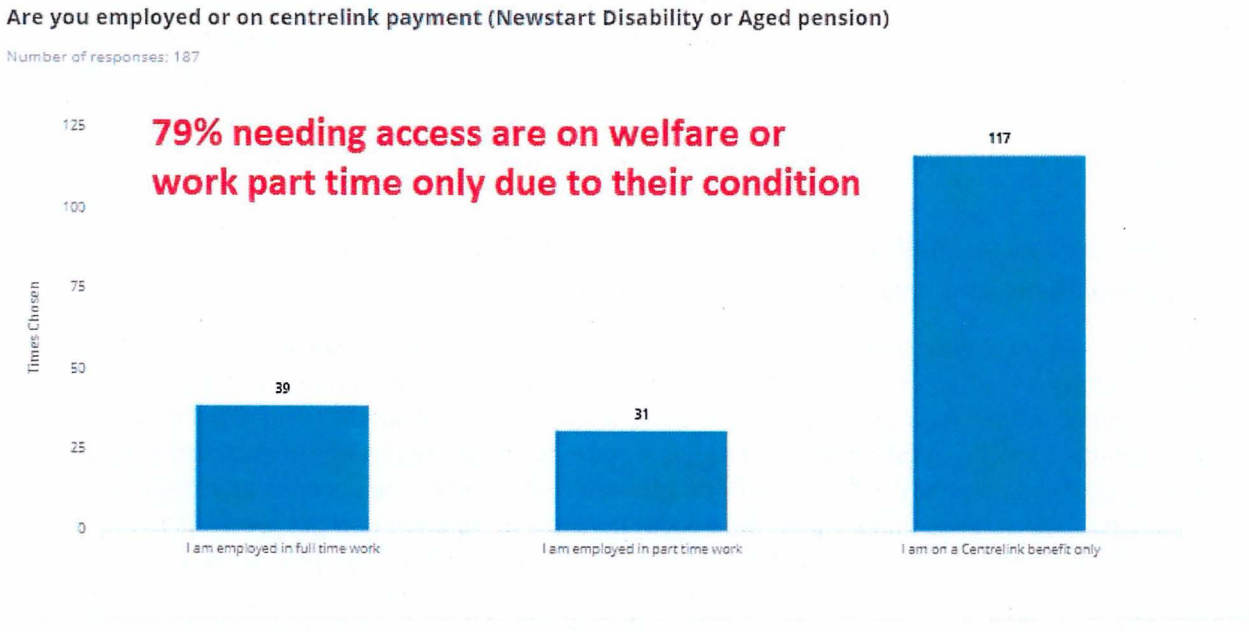
The recently released New Zealand model is also worth some serious consideration … *Patients will have options and choices and everyone can have confidence in the -vaping products, edibles, tinctures, balms, lotions, tablets, softgels, suppositories, transdermal patches and dried flowers. Dried Cannabis can't be supplied for smoking, but patients could use flowers to make homemade remedies. Local commercial production will be allowed and licences are cheaper and simpler than first proposed. ...he scheme looks viable for a local industry to function and get products to market – important for patients and doctors. Locals and small players get a hand up: fees are not prohibitive; local (illicit) genetics can be adopted; local nurseries can supply growers; and imports won't get unfair advantages This is crucial and impressive: doctors need the knowledge to prescribe with confidence and it should come from a trusted independent source ... Costs and time will be greatly mitigated by not requiring clinical trials. This sensible approach recognises Cannabis is not a newly-invented novel pharmaceutical but has a long history of traditional therapeutic uses ... The referendum's Cannabis Legalisation and Control Bill would allow adults to grow 2 plants each, or 4 per household and would permit non profit transfer such as gifting small amounts.*

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

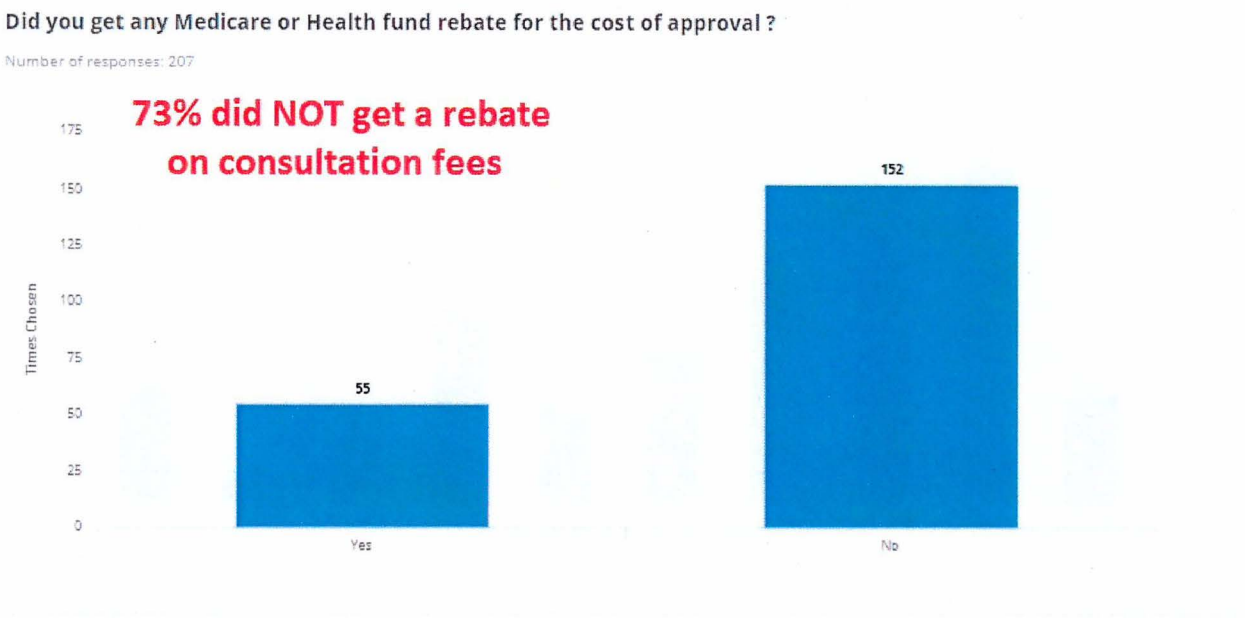
One of the most significant financial barriers to access is **patient income.** Our survey revealed that 79% of patients who need / want access to cannabis are on some form of welfare payment or low income from part time work . Many have been rejected for the DSP – some more than once - again under stringent and cruel policy requirements leaving many on Newstart and surviving on $40 per day.

By far the biggest percentage of medical cannabis users are the socially disadvantaged in our society. Because their medical conditions prevent them from being able to work, they are stuck on the welfare roundabout. It is cruel to make cannabis legally available, but impossible for them to access. The current policy discriminates against vulnerable people with disabilities. Typical of comments we see posted on our group:

> *"…. Who the f**k on $730 a fortnight after rent on a disability pension can afford this the current system denies me on financial grounds and that's so bloody unfair another thing that is utterly unjustified is the ban on driving under the influence of Cannabis why should we lose our independence when we aren't actually impaired at all the whole situation stinks..."*

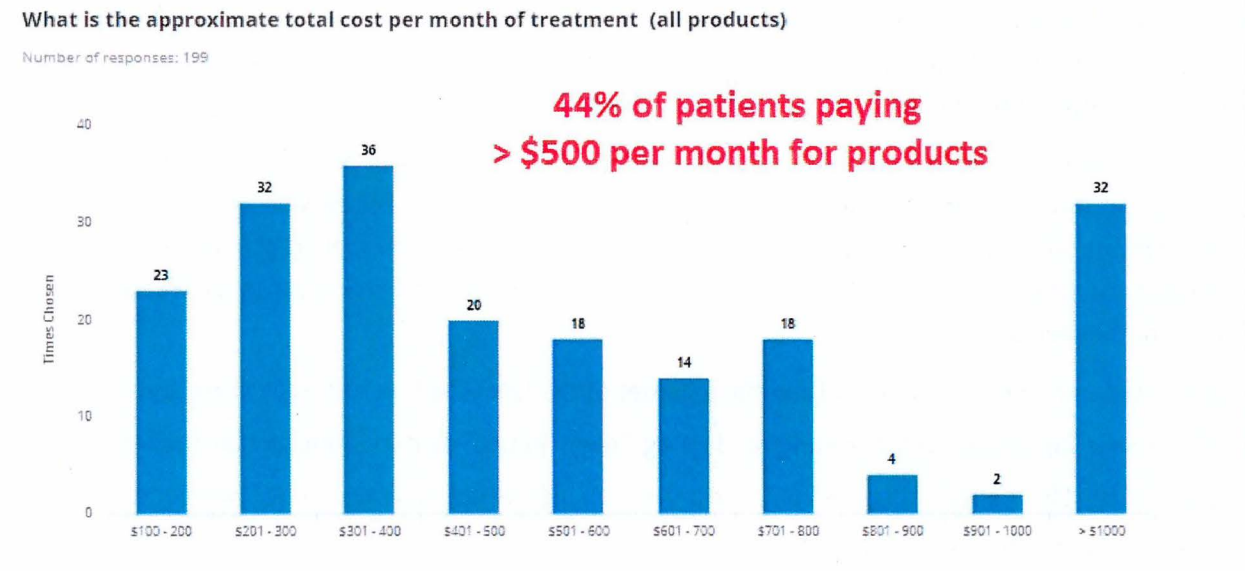


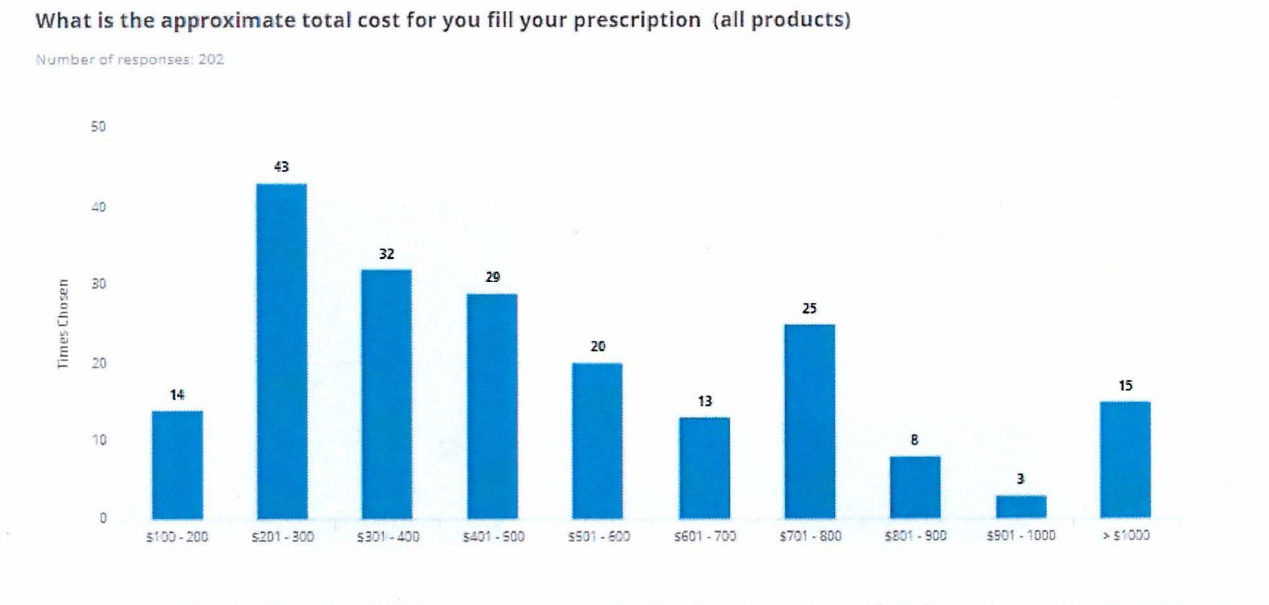
As previously mentioned, **doctor reluctance** pushes people to these corporate clinics where the cost of consulting and monitoring treatment fees, applications fees that in most cases does not qualify for Medicare or Health fund rebate.



This high cost of imported products is also a significant financial barriers to access.

We are continually being told that price will drop as the market expands. While price depends on demand and patient uptake remains low because of cost, it will be a very long time before we see cheaper products. **Even if they were half the current price, many people could still not afford to pay for them.**





The regulatory constraints and demands required by licensees to set up legal grow and/or and manufacturing facilities (indoor grows and high tech security arrangements) have added to the cost of local production. Responsibility to pay shareholder dividends will also be a contributing factor as is the number of hands that a product must pass through (all wanting their cut of the profit pie) before it eventually gets to the patient.

This will no doubt keep the cost of local products high when and if we ever see them readily available. One patient quoted "Aussie" product "Little Green Pharma 10:10 oil it costs $230 (but price does vary depending on pharmacy) and it is 50ml". This is around $50 cheaper than equivalent imports but still out of the reach of many depending on dose needed and frequency of administration requirements.

What the "authorities" have to understand is that laws and policies will NOT STOP patients from seeking out products illegally, or have them risk growing their own. Patients desperate for relief from chronic suffering are hearing and reading about cannabis and the anecdotal evidence that cannabis can improve quality of life, is overwhelming enough for them to want to try it and the black market beckons.

Substantial numbers have and will run the gauntlet of the law which in turn sees more and more patients fronting court, pleading guilty and using "medical use" as mitigating circumstances upon legal advice. The court is obligated to punish them under current State drug laws where there is no defence available for medical use. This process is costly to the public purse and can have severe impacts on the mental and physical well being of patients. And for what purpose? MOST would agree that it is **NOT in the public interest** to continue down this road.

If home growing were an option, patients (or their carers) could produce their own tinctures and oils; balms and edibles and even plug into the health benefits of fresh raw (non psychoactive) cannabis – options that are NOT available to them now via the legal process.

While legal products remain cost prohibitive the Black Market will thrive.

The government should be thinking about integrating these black market entities instead of trying to monopolise the cannabis market and sell standardised cannabis products across the nation. Over regulation adds to the high cost to the end user.

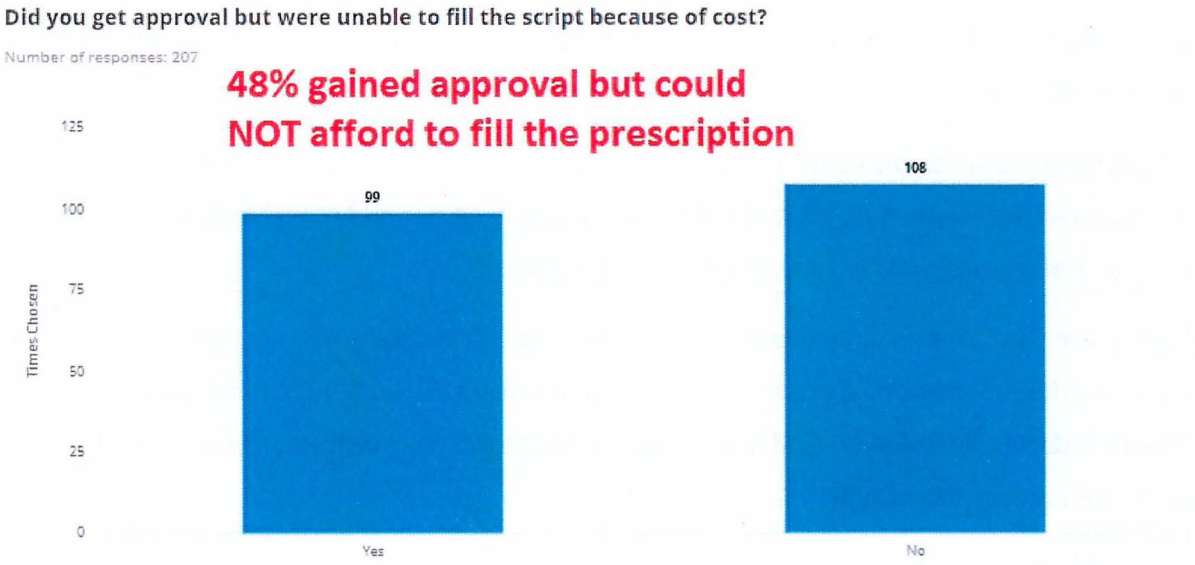
Cannabis access should not be about the "industry". For patients, it is a human/ health rights issue and having the right to consume whatever they choose to improve your quality of life without govt interferance.

(b) the suitability of the PBS for subsidising patient access to medical cannabis products

It appears that the absolute majority of the Australian licence holders are being swallowed up by international companies who gobble up all the locally grown products and send them back to us under their own label at four times the price being charged in their local markets.

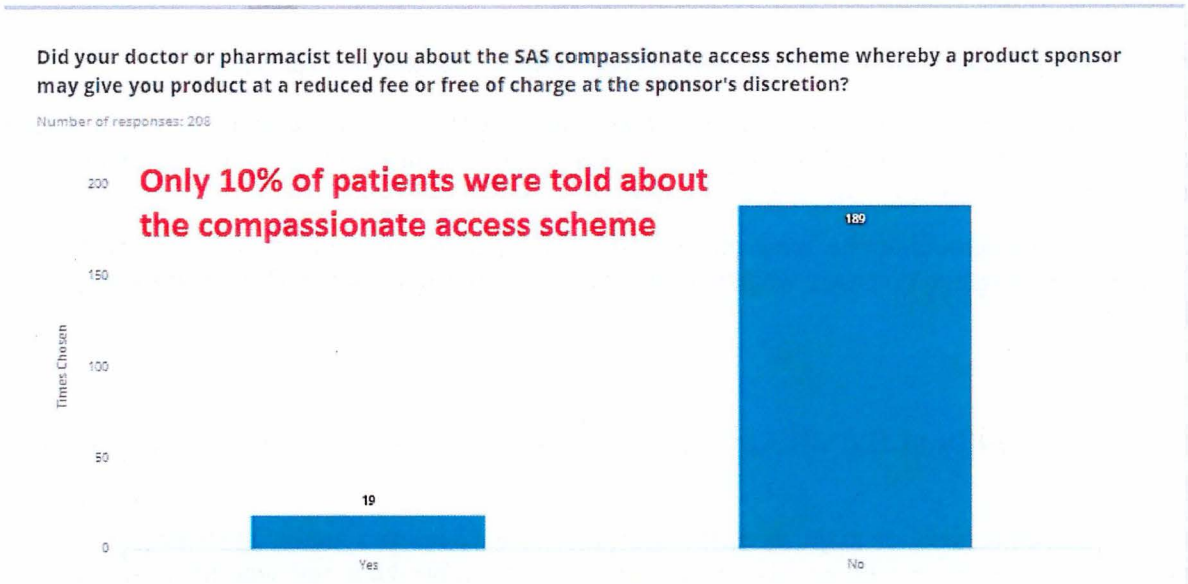
Every day we see **patients crying out for cheaper or subsidised products**. We saw in our survey the prices patients were paying for products.

Pharmacist on A Current Affair episode "Red Tape Madmess" said: "most of the time people come with their prescription and we advise them about the price and MOST instances people say thank you we might look at something else .."



Under the Special Access Scheme product sponsors may choose to provide a good on a compassionate basis where it may attract no fee or be supplied at a reduced cost to the patient, This

is totally at the discretion of the sponsor. Unfortunately, most do NOT mention or offer this to patients and I have not heard of ANY patient who has been granted this concession.



To qualify for PBS subsidy first requires product registration on the ARTG

For a particular product to be registered on the ARTG, a sponsor (usually a company) would need to submit a dossier of evidence on the clinical efficacy, safety and manufacturing quality of a particular medicinal cannabis product to the Therapeutic Goods Administration… At this time, the Australian Government does not subsidise the cost of medicinal cannabis products through the Pharmaceutical Benefits Scheme (PBS). **There is a significant need for larger, high-quality studies to better explore the potential benefits, limitations and safety issues associated with medicinal cannabis treatment across a range of health conditions and symptoms before the Australian Government subsidises the cost of medical cannabis products through the Pharmaceutical Benefits Scheme (PBS).** Kate Wallace Electorate Officer Office of the Hon Stuart Robert MP Federal Member for Fadden

There are currently NO known applications for registration and the likelihood of future applications is probably minimal.

Full TGA approval is complex and costly, thus any product registration and PBS listing will likely be limited to a small suite of oil products of various ratios in carrier oil but no black oil; no juice; no edibles; no leaf; no pessaries or suppositories; and no balms.

Unlike classic pharmaceutical medicines, Cannabis is a multi use medicine - not a one-size-fits all standardised dose to treat one specific condition. It treats many different conditions. Each patient and their needs will be different. And in conditions like chronic pain, each day the level of need varies as we see in our feedback:

> *….They let me buy one bottle at a time 25 mls ($385) and I'm prescribed up to 5 mls a day so at max dose this bottle last 5 days….*

….. script cost $225 - lasted 3 days and I was then offered another product for $380 for 25mls which I declined …. (pensioner stage 4 emphysema who had been making his own black oil for a fraction of that price)….

… I'm being charged $420 for 25ml CBD only I take 1.5 mls per day so just over a fortnight supply…

…. I pay $400 for a 60ml bottle. I have it 3 times a day but fortunately I only have very small amounts so it lasts me quite some time….

If products do become registered and attract PBS subsidy demand could be ***huge*** and the cost to tax payers in the billions at current market prices. This would weigh heavily on the Health Budget.

A Complimentary medicines approach/pathway would be far less costly and keep prices low enough for "user pays". No subsidy would be needed if costs were low enough.

Removing CBD from "prescription only" would allow for online purchases currently banned, but still being used by patients.

Consideration could be given to means testing patients for financial hardship and give a medicare rebate on products to those who qualify.

Or better still, allow patients to grow their own or have a carer grow for them.

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

(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.

The current "official" stance on those driven to the "black" market is around 100,000. Australia's two main advocacy groups - MCUA and United in Compassion (UIC) agree that the number is closer to ***a million*** **Australians who use cannabis for their chronic pain and other illnesses**.

Of those million patients, well under 10,000 are using legal products, leaving 990,000 who are forced to break the law to get relief from suffering.

The uncertainty of ongoing black market supply and fear of being raided by police for home growing are major problems that causes high stress levels that exacerbate existing mental health issues, that go hand in hand with chronic illness.

For those who don't get caught or dobbed in, the benefit is worth the risk. It makes no sense for sick people to be dragged through the judicial system for accessing a medical treatment that is "legally" recognised, but out of reach. The stress and repercussions often cause PTSD adding to patient suffering and results in low public opinion of police personnel.

We had one case, where a patient carrying legal buds was arrested for possession and after spending $7000 on legal fees and months of frustration and mental anguish the court threw the case out. This left him in debt he could not be compensated for and increased his depression and anxiety. Police need to have clear legislative directions in cases of medical use and less reliance on "discretion".

Random roadside saliva testing is another HUGE worry for medical users of cannabis. A zero tolerance policy exists nationwide. Because of its unique situation of being both illegal and legal no dispensation has been made for medical users.

NO other **legal medication** is treated in this way. Patients do not have to stop taking morphine based drugs or Benzodiazepines 4-5 days before they drive for fear of being **RANDOMLY** tested at a roadside blitz, charged with an offence and losing their license for having **presence** only in their saliva.

"...Australia's drug driving laws criminalise individuals who represent no risk to other drivers, making a mockery of the law as a tool for reasonably managing risk in a community, writes ***Greg Barns****. In most states and territories the court will have no choice but to disqualify or cancel a first time offender's drivers licence for a period of between a minimum of three months and maximum of six to nine months.*

Drug driving laws are grossly unfair. They are not based on data or scientific knowledge. Dr Alex Wodak.

*"..The link between alcohol and road deaths and injuries is well known. We base our drink driving laws on this demonstrably correct (****scientific****) data and accordingly allow for some alcohol in the bloodstream for full drivers licence holders, so long as it is below a blood alcohol content of 0.05 per cent.* ***But not so with other drugs such as cannabis****. Here we take the prohibitionist stance and apply it to driving ....* ***Australia's drug driving laws have no evidential basis but can have severe impacts on the rights of individuals and their families and loss of a drivers licence can mean losing your job.. "***
https://www.abc.net.au/news/2016-01-29/greg-barns-drug-driving-laws-are-unfair/7116994

Driving Under the Influence is a different matter and is only used when someone is seen to be driving erratically. Presence at random roadside test sites, does not always equate to impairment and infact many of our members say without cannabis their driving ability is far more impaired by pain or anxiety, than by cannabis medications.

Authorities such as ***National Drug Driving Working Group*** need to recognise that presence of cannabis does not always equate to putting other road users at risk.

Now we are hearing (in NSW at least) that the tests will be increased to 200,000 this year. This has stuck panic into the hearts of medical users especially in regional and rural areas where public transport is non existent; and the implications they will experience through loss of license and those related to vehicle insurance weigh heavily on their mental health.

Aside from the fear of being RANDOMLY tested, we are hearing from members (**and this is backed up by a study at Sydney University last year**) that the products used to test drivers are unreliable and inaccurate and can give both false negatives and false positives.

There is no advice being given re how long after medicating patients will be safe from a positive result. Up until 9th Dec the RMS website in NSW gave 12 hours as the estimate for getting a negative result but that has since been changed to:

"...The effects of drug use depend on the type and concentration of the drug taken and vary widely between individuals. In the case of illicit drugs, the exact chemical substance, dosage and duration of the effects can be difficult for users to estimate..."

People on medical cannabis would be equal to " chronic, frequent users (who) will also experience a rapid loss of THC from their blood after smoking, but they will also have a constant, **moderate level of blood THC even when they're not high."**

So it is really a case of Random Roadside Roulette for revenue raising and in the case of medical cannabis use, random testing has nothing whatsoever to do with road safety issues.

https://sydney.edu.au/news-opinion/news/2019/09/12/study-casts-doubt-on-accuracy-of-mobile-drug-testing-devices-.html

See Appendix for more information on driving issues.

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

There are over 25 thousand credible published studies in PubMed that cover both positive and negative coverage of medical cannabis and many other credible libraries online.
https://www.ncbi.nlm.nih.gov/pmc/?term=cannabis

Granny Storm Crow's List is updated every year *"...The first studies section is devoted to the more recent medical studies and articles from 2010 to 2019. The older studies go into detail about some of the basics (storage of Cannabis, effects on hormone levels etc). The older studies also tend to be easier to understand, so they are a good place to begin your education...."*
https://grannystormcrowslist.wordpress.com/the-list/

There is an online course teaching Australian doctors the basics that is worth CE points for less than $200 tax deductible dollars. https://mcra.medihuanna.com/

There are other trusted online courses from reputable US providers such as The Medical Cannabis Institute Global also worth CE points. *"TMCIGlobal provides online medical education for healthcare professionals who want to learn about medical cannabis and its potential clinical application. Our science-based, accredited courses help professionals deliver quality care and address patient questions…. In order to deliver the best in medical cannabis education, TMCIGlobal offers content from experts in medical cannabis. Collectively, these experts have been educating healthcare professionals for over 50 years."* https://themedicalcannabisinstitute.org/course-catalog/.

Each year UIC have had a symposium featuring well respected international cannabis specialists.

Twice a year the Hemp Health and Innovation Expo (HHIE) also holds a series of lectures. These have been held in Melbourne, Sydney, Brisbane and this year will be in the ACT.

Medicann 2 day workshops are held on a regular bi monthly basis in Nimbin NSW. These are very well attended and inexpensive. They feature doctors, lay healers, patient testimonials, industry representatives and legal information by qualified solicitors.

Doctors should not be educated by people in the industry as is the case with the "charitable" arm of an organisation heavily invested in import, distribution and sales of cannabis products. This could be seen as a good way to market products to a captive audience.

Patients are often a well informed source of information, as they tend to have an interest and passion for learning about the plant. Not sure that most doctors carry such a passion for natural medicine.

Lay healers in the Cannabis community specialise in whole plant cannabis treatments and often teach skills to the people in workshops or one on one sessions.

I think it all boils down to the individual doctor as to how much interest / passion / curiosity they have to seek new knowledge that is truth and not the propaganda they have been fed for decades. This will take some getting over. One of my GP s told me he didn't want to "learn a whole new set of skills at 50" and another just last year told me he thought cannabis was "a fad" - and now two years later his surgery has a willing prescriber.

Conclusion

"Cannabis can never be a pharmaceutical agent in the usual sense of medical prescription as it contains a variety of components of variable potency and actions, dependent on its origin preparation and route of administration. Consequently cannabis has variable effects in individuals. It will not be possible to determine universally safe dosage of cannabis for individuals based on a clinical trial." **David G Pennington DM FRCP FRACP University of Melbourne Vic.**

1. Cannabis is a herbal medicine. It could/should be delivered via the Complementary pathway under current legislation.

2. A complementary delivery model would allow smaller players to enter the local market creating employment; utilising existing skill base, and increasing the variety of products and strain choices. We have a huge skills and knowledge base in the cannabis community that should not be wasted. This type of delivery model could legitimise current illegal "dispensaries" and enable a dispensary model to be put in place locally, which could also supply Herbalists and/or compounding chemists.

Under this pathway, patients could be granted the option to self grow, possibly with certain conditions attached - like keeping plants from public view and away from children etc.

3. A local herbal based delivery system running in parallel with the current pharmaceutical model would give patients a choice. Patients who prefer GMP products with standardised dosing are already being catered for. Those who prefer to grow and make their own or have a "carer" or dispensary prepare their individual needs are not being supported by the current model.

4. If the current situation continues, there needs to be changes made to the State's Drugs Misuse Acts to reflect the increasing number of patients who use illicit cannabis for medical use because they cant get legal access; and formalise police "discretion" into law that will protect patients from prosecution, if they choose to self supply for legitimate medical reasons for use.

5. Drug driving issues also need to be addressed urgently . Zero tolerance does not work with a medical cannabis program. Many recent studies are showing that Cannabis users are not a threat to the safety of other road users. (see appendix attached)

"… Labor ... acknowledges the view of many patients and advocates that the TGA system will never be fit-for-purpose for medicinal cannabis. This view has emerged after years of frustration under the Liberals… Labor wants to encourage competition and choice in the domestic medicinal cannabis market, which will contribute to a consistent and affordable supply of product over time…" ***https://www.change.org/p/decriminalise-the-use-of-medicinal-cannabis-for-people-with-terminal-cancer-like-my-son/responses/42198***

In the words of ***Prof. Iain McGreggor, Lambert Initiative, Sydney University*** *"...There are several steps that could be taken to better meet community expectations: an* ***amnesty for current users of illicit cannabis products*** *with verified medical conditions would* ***be a good start****. …..Rescheduling of non-intoxicating, low-THC cannabis products as over-the-counter medicines might also be considered. When manufactured according to best practice, these products are no more hazardous than many of the nutraceuticals on pharmacy shelves.* ***Let's rethink our strategy*** *and make medicinal cannabis products readily available to Australians in need…."*

https://www.smh.com.au/opinion/why-so-few-australians-are-using-medicinal-cannabis-on-prescription-20171008-gywqq7.html

By far the best solution for patients would be to legalise cannabis for all its uses at a Federal level. But we all know that will not happen while the LNP are in power. Many patients and social users know that it is inevitable that legalisation will occur "somewhere down the track" as other commonwealth countries, who are signatories of UN treaties, have chosen to do.

The LNP have stifled debate on the subject. Refusing to allow a plebiscite on the question of legalisation as requested in a well supported Parliamentary petition in 2018.

It is unclear where the ALP stand on the legalisation issue.

However, recent media polls have showed an average of 80% of "The People" think legalisation for adult use is a good idea especially patients who cannot afford access to legal products. Which leaves us to question: When rest of the world is winding down its War On Cannabis WHY is Australia, ramping it up ... more police, more dogs, more strip searches, more arrests for personal use?

Again, thank you for the opportunity to express our opinions on this issue.

Yours Sincerely

Gail Hester
Founding Member MCUA of Australia and

Executive Committee MCUA of Aust. Inc.

DRIVING IMPAIRMENT Appendix 1

There is a lot of misinformation flying around about these lick a stick saliva tests.

*"...**A major inconsistency in the state's roadside drug testing regime has emerged** ..Dr Judith Perl of the police's Impaired Driving Research Unit made the admission while giving evidence…*

*When questioned in general terms about the effectiveness of the police's oral testing method in detecting different types of cannabis consumption, Dr Perl said: **'if it is ingested it will disappear out of the oral fluid very rapidly, or if it is ingested in a capsule form it will not even be detected [at all]**'…..*

*'The uncontradicted evidence of Dr Perl is unequivocally that if you **take THC orally by capsule or by suppository then it is not possible to have a level of THC detectable in oral fluid**,' (Magistrate) Heilpern said. ".. **the only available conclusion from government's own expert is that criminal liability depends on the mode of intake. ...this also means that someone could be significantly affected by cannabis, but escape detection by police because they had taken a capsule, while a person who had smoked cannabis 24 hours earlier and was no longer affected, would face prosecution.***

NSW Police minister David Elliot refused to comment on the inconsistency when contacted byThe Echo, instead passing the questions on to the NSW Police Media Unit.
https://www.echo.net.au/2019/04/roadside-drug-testing-flaws-exposed-local-court-case/

The feedback from the public via a Facebook survey question re this issue:

"... I have tested positive, I was doing a range test in name of science
No smoking or vaping was done .. had oil (mct base) and tested half hourly till a negative. First negative @4 hours post dose ..."

"..... ONE hour after taking oil (no smoking or vaping) 12 weeks loss of licence and because road side testing doesn't tell you the amount you have in your system just that it showed up there is nothing you can do ....."

"... a couple of friends have tried the strips n both show a low level. Both take 0.01ml only of FECO/olive oil 4xs a day, 1 of the 2 stripes showed positive each time, no smoking or vaping....."

" .... I did a tincture under the tongue. was supposed to be CBD only but had thc was positive the next day ...."

".....tincture under the tongue. Got a section 10. I was treating a headache the night before. Nothing on the day ...."

Cannabis is a very individualised medication. It works differently in all persons. One cannot make broad sweeping claims that will apply to everyone who uses it.

RELATED STUDIES

Few differences were observed between smoked and vaporised Cannabis administrations ... Cannabinoid concentrations peaked immediately after -consumption, regardless of route, as a result of oral mucosa contamination. As expected, greater THC concentrations were observed after smoked and vaporised Cannabis compared to oral administration. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5357602/?fbclid=IwAR3g69_R6AtgqNb3GyNhhMk9rygX26wuALN2rJkcIRAvYfMfLtzPJMeKtkk

Disposition of cannabinoids in oral fluid after controlled around-the-clock oral THC administration
https://www.researchgate.net/publication/44656460_Disposition_of_Cannabinoids_in_Oral_Fluid_after_Controlled_Around-the-Clock_Oral_THC_Administration?fbclid=IwAR3De4_moZCfijrcFfJZ4dE0WEWA2T4syqi7Er4LYrluEC6METlFmWdxvuM

Can oral fluid cannabinoid testing monitor medication compliance and/or cannabis smoking during oral THC and oromucosal Sativex administration

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612560/?fbclid=IwAR1JPnHCfIPOm6m5eA7yZUaXvthUiuK0_lxZNoqHo6K01CInTLlzVM33wRs#!po=12.5000

First of its Kind Study Finds Virtually No Driving Impairment Under the Influence of Marijuana May 2018

Researchers at the University of Iowa's National Advanced Driving Simulator carried out the study, sponsored by National Highway Traffic Safety Administration, National Institute of Drug Abuse, and the Office of National Drug Control Policy.. **In fact, some would argue that it makes them drive** safer or slower. The study's findings further illuminate the fact that alcohol is a much more dangerous drug than cannabis, and somehow the former is legal while the latter is not… ***the study also found that analyzing a driver's oral fluids can detect recent use of marijuana but is not a reliable measure of impairment…*** *drivers with blood concentrations of 13.1 ug/l thc, showed increased (lane) weaving that was similar to those with a .08 breath alcohol concentration,*

http://ushealthmagz.com/2018/05/02/first-of-its-kind-study-finds-virtually-no-driving-impairment-under-the-influence-of-marijuana/

Study: Marijuana Use Results in Decreased Speed, No Negative Effect, on Driving

November 21, 2019

According to a newly released study subjects who consumed cannabis typically decrease their driving speed and demonstrated few other significant changes. The study, titled *Acute and residual effects of smoked cannabis: Impact on driving speed and lateral control, heart rate, and self-reported drug effects,* was published in the journal *Drug and Alcohol Dependence.*
https://thejointblog.com/study-marijuana-use-results-in-decreased-speed-no-negative-effect-on-driving/?fbclid=IwAR0peaXmzWqcxHXwMXDESLJLEVcO-r55t6FoI2rkh_f-nm30ZuZG_L9tJes

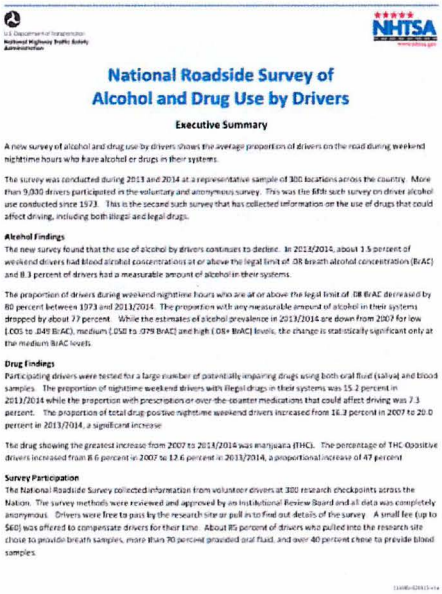
Germany: Drivers on cannabis will no longer automatically lose license April 2019

Drivers caught driving under the influence of cannabis will no longer automatically lose their licenses. Experts have argued that cannabis users can still have THC in their blood even days after consumption.

https://www.dw.com/en/germany-drivers-on-cannabis-will-no-longer-automatically-lose-license/a-48295955?maca=en-Facebook-sharing&fbclid=IwAR0Xzmw2FRusztzgfpPcJJqvwr3XjVTA3PvvJ_OMm344xVduAHTB8lx_TgE

Introducing **DRUID (DRiving Under the Influence of Drugs) the public health app** testing for cannabis – **measuring your level of competency essential to skillful driving.**

https://www.healtheuropa.eu/a-paradigm-shift-in-impairment-testing-for-cannabis-the-druid-app/94154/



National Roadside Survey of
Alcohol and Drug Use by Drivers

Executive Summary

A new survey of alcohol and drug use by drivers shows the average proportion of drivers on the road during weekend nighttime hours who have alcohol or drugs in their systems.

The survey was conducted during 2013 and 2014 at a representative sample of 300 locations across the country. More than 9,000 drivers participated in the voluntary and anonymous survey. This was the fifth such survey on driver alcohol use conducted since 1973. This is the second such survey that has collected information on the use of drugs that could affect driving, including both illegal and legal drugs.

Alcohol Findings

The new survey found that the use of alcohol by drivers continues to decline. In 2013/2014, about 1.5 percent of weekend drivers had blood alcohol concentrations at or above the legal limit of .08 breath alcohol concentration (BrAC) and 8.3 percent of drivers had a measurable amount of alcohol in their systems.

The proportion of drivers during weekend nighttime hours who are at or above the legal limit of .08 BrAC decreased by 60 percent between 1973 and 2013/2014. The proportion with any measurable amount of alcohol in their systems dropped by about 17 percent. While the estimates of alcohol prevalence in 2013/2014 are down from 2007 for low (.005 to .049 BrAC), medium (.050 to .079 BrAC) and high (.08+ BrAC) levels, the change is statistically significant only at the medium BrAC levels.

Drug Findings

Participating drivers were tested for a large number of potentially impairing drugs using both oral fluid (saliva) and blood samples. The proportion of nighttime weekend drivers with illegal drugs in their systems was 15.2 percent in 2013/2014 while the proportion with prescription or over-the-counter medications that could affect driving was 7.3 percent. The proportion of total drug-positive nighttime weekend drivers increased from 16.3 percent in 2007 to 20.0 percent in 2013/2014, a significant increase.

The drug showing the greatest increase from 2007 to 2013/2014 was marijuana (THC). The percentage of THC-positive drivers increased from 8.6 percent in 2007 to 12.6 percent in 2013/2014, a proportional increase of 47 percent.

Survey Participation

The National Roadside Survey collected information from volunteer drivers at 300 research checkpoints across the Nation. The survey methods were reviewed and approved by an Institutional Review Board and all data was completely anonymous. Drivers were free to pass by the research site or pull in to find out details of the survey. A small fee (up to $60) was offered to compensate drivers for their time. About 85 percent of drivers who pulled into the research site chose to provide breath samples, more than 70 percent provided oral fluid, and over 40 percent chose to provide blood samples.

Drivers who test positive for the presence of THC in blood **are no more likely to be involved in motor vehicle** crashes than are drug-free drivers, according to a federally sponsored case-control study involving some 9,000 participants. The study, published Friday by the United States National Highway Traffic Administration (NHTSA), is the first large-scale case-control study ever conducted in the United States to assess the crash risk associated with both drugs and alcohol use by drivers.
https://www.nhtsa.gov/press-releases

THC false positives are too frequent and the consequences can be devastating for thousands of people October 2019

The issue of THC false positives affects thousands of people in the military, people who could lose their jobs, people who could lose custody of their children and people who could go back to jail for having broken the conditions of probation for consumption of THC.

THC false positives in drug tests are one of the many problems that arise as police authorities do what they can to catch up with the changing laws of the modern cannabis industry. An example of this is the fact that there is no exact test or threshold to measure the psychoactive effects of cannabis. The best evidence at the moment can only show if a person has used cannabis in recent

days. This makes it almost impossible to determine if a person drives while under the influence of THC

https://www.cannabisground.com/thc-false-positives/?fbclid=IwAR0eSEmUWGc3KkxkodGN3YXIsoTuPdEezJ-xFcpceSlsfQB5-S2aP45KM_0

"**There is no one blood or oral fluid concentration that can differentiate impaired and not impaired**," says Marilyn Huestis, who spent over 20 years leading cannabinoid-related research projects at the National Institute on Drug Abuse.

"**It's not like we need to say, 'Oh, let's do some more research and give you an answer.' We already know. We've done the research.**"
https://www.sciencedaily.com/releases/2018/01/180125135606.htm

Why Is It So Hard To Test Whether Drivers Are Stoned? February 2016

THC, dissolves in fat, whereas alcohol dissolves in water… And that changes everything. "It's really difficult to document drugged driving in a relevant way," says Margaret Haney, a neurobiologist at Columbia University who headed the chemistry and drug metabolism section at the National Institute on Drug Abuse. .. It absorbed in a very different way and much more difficult to relate behavior to [blood] levels of THC or develop a breathalyzer… **The height of your intoxication isn't at the moment when blood THC levels peak,** and the high doesn't rise and fall uniformly based on how much THC leaves and enters your bodily fluids.. But daily users are different... heavy smokers build up so much THC in their body fat that it could continue leaching out for weeks after they last smoked. These chronic, frequent users will also experience a rapid loss of THC from their blood after smoking, but they will also have a constant, **moderate level of blood THC even when they're not high**, Huestis says.
https://www.npr.org/sections/health-shots/2016/02/09/466147956/why-its-so-hard-to-make-a-solid-test-for-driving-while-stoned

Screening for Impairment November **2018**

With no blood alcohol concentration equivalent test and no accepted standard to measure impairment, **police are only able to rely on screening methods and behavioral indicators to identify impaired drivers**. A California Highway Patrol (CHP) spokesperson (said) that some of the behavioral indicators include poor driving, signs and symptoms of impairment, and poor performance on field sobriety tests… The field sobriety tests, designed to mimic the mental skills needed for driving, include checking for involuntary jerking of the eyes, and testing whether the driver can divide their attention between a mental and physical task.
https://www.theepochtimes.com/what-makes-testing-for-marijuana-impairment-so-challenging_2707110.html

The Standardized Field Sobriety Tests (SFSTs) are a battery of tests performed during a traffic stop to determine if a driver is impaired. Although there are a number of different field sobriety tests, three have been scientifically validated by the NHTSA and are generally admissible in court (Burns, 2013): 1. Horizontal gaze nystagmus (HGN): The subject is instructed to follow the movement of a light (or finger or other object) with only the eyes and no head movement;

impaired subjects cannot follow the movement smoothly and a distinct jerk will appear prior to 45°. 2. Walk-and-turn test (WAT): The subject must walk nine heel-to-toe steps on a line, turn, and return along the line with nine heel-to-toe steps. 3. One-leg stand (OLS): The subject must raise one leg and hold it ~6 inches up while counting slowly until told to stop (at 30 seconds). April 2019

http://media.graytvinc.com/documents/Michigan+Impaired_Driver_Report_1553554601148_79160282_ver1.02.pdf

Comment These kinds of tests are subjective and open to "interpretaiton" by the officer. People with disabilities often cannot physically perform such tasks whether they be impaired or not.

Job Advertisement for clinic doctors Appendix 2

GP required for specialist cannabinoid clinic

Emerald Clinics - Richmond VIC
Part time

About us

Emerald clinics is a specialist referral service for patients who are candidates for a therapeutic trial of cannabinoid medicine (Medical cannabis) staffed by trained multidisciplinary clinical teams. Our mission is to improve lives, by learning from the experience of every patient that is treated within our model of care.

The Emerald Clinics model enables patients to be referred from their treating clinician for the specific purpose of a trial of cannabinoid medicine. Our clinicians work collaboratively with our patients' broader care team to ensure information is shared and the broader care team retains clinical leadership for other aspects of the patient's treatment.

Find out more at www.emeraldclinics.com.au

About the role

- In person consults conducted from our clinic in Richmond within a private oncology practice
- Working in our multidisciplinary clinic you will
  - Assess patient suitability for a trial of medicinal cannabis
  - Prescribe and monitor patient outcomes
  - Interface with regulatory bodies as required with the support of an experience clinical administration team
- Flexible position on offer
- Attractive day rate remuneration
- Support for education and conference attendance
- Ongoing cannabinoid medicine training for successful applicants

About you

- At least 3 years experience in General Practice
- Current unrestricted registration with the AHPRA
- Vocational Registration as a General Practitioner
- Your own medical indemnity insurance
- Would suit experienced clinician looking for work/life balance or returning to work
- Interest/Experience in clinical research a plus
- Experience treating patients with medicinal cannabis a plus

For immediate consideration, please submit your CV through SEEK. Only successful candidates will be contacted. Australian citizens and permanent residents need only apply.