MCANZ

MEDICINAL CANNABIS IN AOTEAROA:

A COMPREHENSIVE SOLUTION FOR 2018 AND BEYOND

CONTENTS

GLOSSARY

Licensed Producer (LP)	• A vertically integrated company engaged in cannabis cultivation and product manufacture.
Cannabinoids	• The group of primary active ingredients in cannabis. These compounds can occur in other plants in rare instances.
THC	• Tetrahydrocannabinol, a primary cannabinoid. THC has clinically proven therapeutic effects, particularly on spasticity, involuntary movement, pain and nausea. It is also the compound responsible for the psychoactive effects of cannabis.
CBD	• Cannabidiol, another primary cannabinoid found in particular strains of cannabis. CBD has shown benefit in epilepsy, anxiety disorders, inflammation and immune disorders. It can also partially negate some side-effects of THC, including psychoactivity.
CBDV, THCV, CBC & CBG	• Minor cannabinoids which are less researched and understood, but also have been demonstrated to have therapeutic properties.
Terpenes	• The secondary chemicals in cannabis that impart specific aromas and flavours, and have medical benefits in their own right. These compounds are generally less understood than the main cannabinoids.
MOH	• Ministry of Health
CBP	• Cannabis-based products. The Government's preferred terminology for cannabis medicines.
Fentanyl	• An opioid 50-100 times stronger than morphine.

YES TO MEDICAL CANNABIS, BUT *WHAT'S NEXT?*

Our model medical cannabis law is based on research, with input from lawmakers, medical professionals and most importantly, the patients. Our aim is to maximise access for patients, while at the same time minimising costs to both patients and government agencies, and reducing the potential for diversion to the illicit market. While we recognise that significant change on recreational cannabis is a possibility in the mid-term, this policy assumes no change in that arena; it is not intended to be a step toward recreational cannabis.

From countless polls and surveys, we know that a strong portion of the country supports medical/compassionate use of cannabis. The Labour government has promised some changes, and has put forward a rescheduling of a single compound, CBD, while suggesting domestic production as an option. Additionally they have proposed an exemption for terminal patients, which in our opinion would prove redundant if the police were following the public interest test of the Solicitor General's prosecution guidelines. Counter to this, a member's bill currently in the name of Chloe Swarbrick delivers what many patients want: the right to possess and cultivate their own cannabis.

We outline a solution that MCANZ believes will build on the lessons from other international jurisdictions to give New Zealand one of the best medical cannabis systems in the world. There are myriad medical cannabis regulatory regimes around the world, from state to national level; the challenge for us is to pick a solution, and adapt it to New Zealand conditions, to the satisfaction of the medical profession and the patient community. Failure to do so will continue the current situation, with police targeting medical users. The medical profession is currently being compromised as more and more doctors feel they have no choice but to suggest illicit use of cannabis as a viable treatment due to the costs of legal options. A comprehensive change is needed.

This model medical cannabis law is intended to be a workable template for what New Zealand can achieve with an appropriate level of political will.

WE PROPOSE :

- Allowing a domestic industry to make cannabis-based products (CBP).
- Treating CBP in the same way as other controlled drugs for prescribing purposes.
- Allowing individuals to cultivate for medical purposes under a tight regime.
- Inserting 'medical necessity' as an explicit defense in court.
- Setting up a separate Pharmac funding scheme for CBP.

THE GOALS OF THE POLICY

1. Supply the lowest cost product to patients. We already have legal medical cannabis, but at eye-watering prices which put products out of most people's reach.
2. Eliminate criminalisation of medical patients. Even with lenient courts, tens of thousands of patients are currently criminals and fear the police.
3. Respect human rights. In other Western jurisdictions, the ability to make one's own medicines has been recognised as a basic human right.
4. Encourage a domestic industry. Opening up medical cannabis access will either enable NZ job creation, or result in tens of millions of dollars going offshore.
5. Encourage NZ-based research and trials. Clinical trials are cheaper to do in New Zealand than in most developed countries, an advantage we can exploit as cannabis becomes more mainstream.

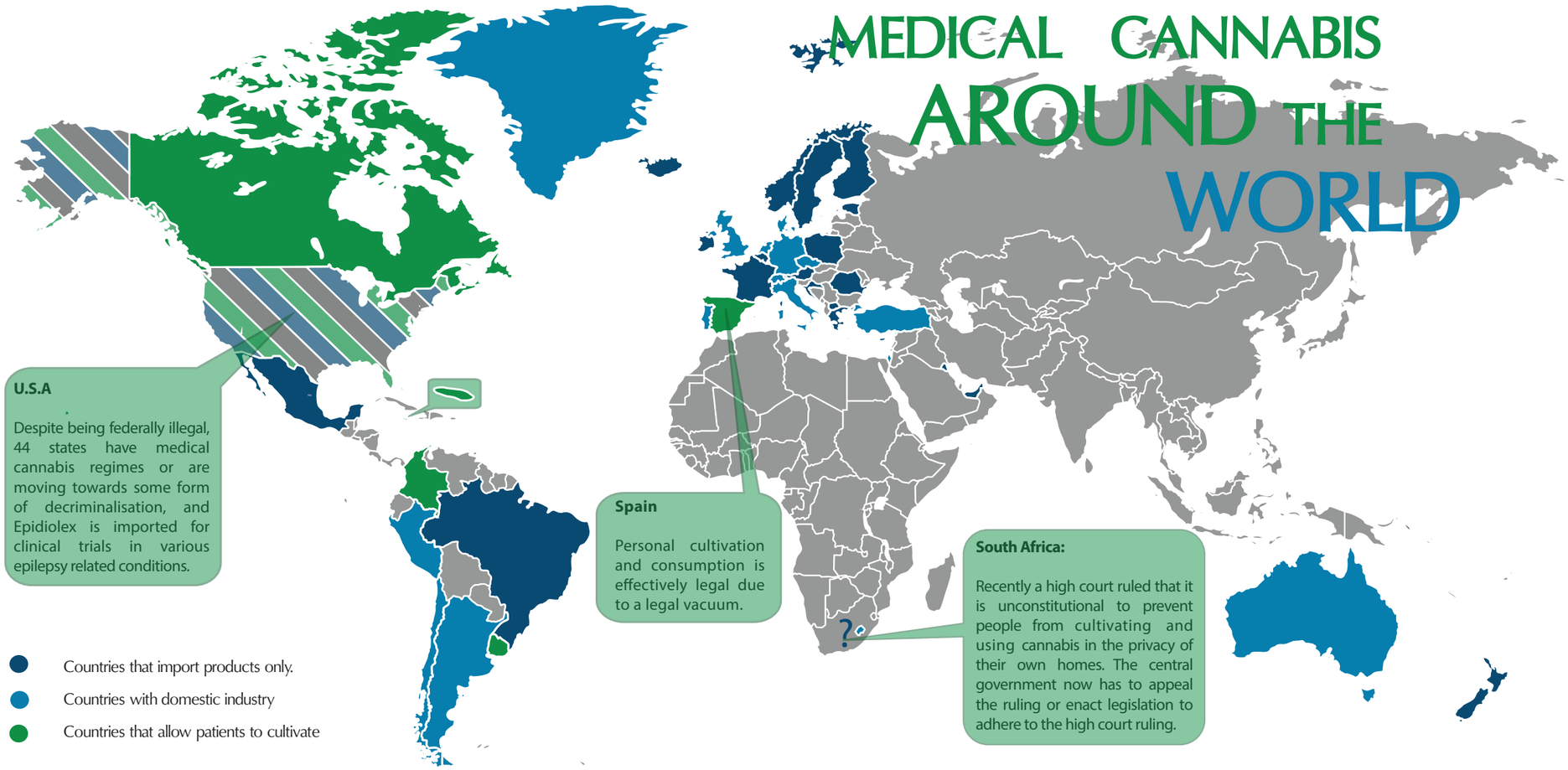
PATIENT POPULATION

Currently, New Zealand has a slow trickle of legal medical cannabis patients. The crippling costs of importation and strict Ministry of Health criteria have kept patient numbers low. MCANZ has been working to champion non-pharmaceutical products in order to obtain lower costs for patients. Surprisingly, we have helped patients pass the Ministry of Health review process to obtain four different products from Canada, each with varying cost savings over New Zealand's only registered cannabinoid medicine, Sativex. However, our estimate is that perhaps approximately 70 people have legal access at any one time in New Zealand, due to the crippling costs.

Looking to other countries, we can get a gauge of the potential cannabis patient population by extrapolating international numbers to New Zealand's population. New Zealand would have 15,000+ patients under a conservative regime such as Israel's, while a more permissive regime such as Canada would have 25,000+. New Zealand cannabis use surveys are harder to interpret, as adult users may use cannabis for therapeutic purposes on occasion, and vice versa.

In New Zealand, medical conditions which have good scientific evidence for therapeutic benefit from cannabis are currently underserved. Most multiple sclerosis patients cannot afford the legal option that can be prescribed to them, and so many are not offered Sativex even when appropriate. Patients with severe MS are unable to work, and the various WINZ benefits are not enough to cover the cost of what we consider an essential medicine for many. Patients with other conditions are underserved by professional resistance, due to doctors' lack of familiarity with medical cannabis. Specialists in pain medicine have been noticeably resistant, in spite of consistent scientific evidence that cannabis relieves chronic pain.

MEDICAL CANNABIS AROUND THE WORLD



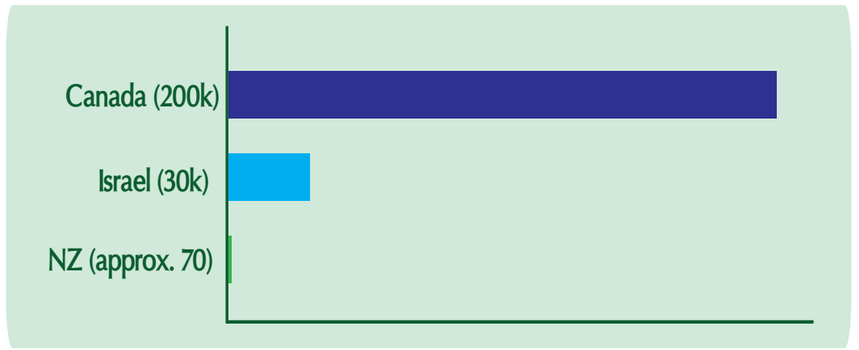
12% of NZ cannabis users use it mostly or solely for medical purposes.

-Global Drug Survey 2017

There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

- The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. National Academy of Sciences 2017

PATIENT POPULATION PER COUNTRY.



INTERIM MEASURES TO PROTECT PATIENTS' RIGHTS

Due to the time it takes to implement substantial law reform, we recommend a series of urgent interim measures to improve medical cannabis access while the Government works toward more comprehensive law reform.

Authority to Prescribe

Through advocacy for individual patients, MCANZ has uncovered significant support amongst General Practitioners for patients with the most extreme conditions. However, the current system requires specialists to be involved in prescribing cannabis. This is often problematic; pain specialists in particular have been obstinate in their refusal to apply for cannabis-based products. The most sensible interim measure is to enable GPs to be treated as equals to specialists, allowing them to apply to prescribe under the MOH non-pharmaceutical application pathway. Cannabis-based medicines are fairly benign in their side effect profile, and the most common condition for which they are likely to be used is chronic pain.

This simple change will in the short term enable more doctors who favour medical cannabis to prescribe it. It will also incentivise prescribers to become more educated.

Medical Necessity and the Courts

Police continue to prosecute medical users and their suppliers relentlessly. The police prosecution guidelines include a clause which allows them to take the health of the patient into account, which could allow the police to leave the sick alone, but in practice this rarely happens. If the patient is very ill, police sometimes prosecute a family member instead, if cultivation is the offence. On occasion, police will use the 'shotgun' approach and charge married couples in order to extract a confession out of one.

Some patient groups are lobbying for a moratorium on cannabis prosecutions of medical patients. Implementing this would necessitate an official register of medical patients, which would require medical signoff of some sort for patients to be covered.

In isolation from other law changes, we recommend enshrining a robust definition of medical necessity in two places. Firstly, we recommend a review of the "public interest test" in the Solicitor General's prosecution guidelines, with a view to inserting a clause around breaching drug laws for "significant therapeutic benefits". Secondly, we recommend an insertion of medical necessity into the Crimes Act to be used as a legal defence by medical users. This would forge a court-enforced culture change in the police. Some judges have already expressed sympathy for patients before the courts and have either given them token sentences or granted discharges without conviction. However, despite these lenient court judgments, the effects on patients and their families from prosecution can still be catastrophic. Stress, anxiety, deprivation of an essential medicine, and large legal bills are par for the course. Legal bills are particularly burdensome for the many patients who are on WINZ benefits or ACC income replacement due to their medical conditions. It is for this reason MCANZ does not support the incomplete solution offered to terminal patients by the current Government. A formalised medical necessity pathway would result in more cases being thrown out of court, with positive flow-on effects on police prosecuting habits.

Medical Cannabis Training

The main barrier to access at the moment, other than cost, is the reluctance of prescribers, primarily due to lack of education. To accelerate uptake for legitimate patients, prescriber education is necessary. We recommend that the Ministry of Health facilitate this. Some schools of medicine have been particularly intransigent about medical cannabis. In our experience, many neurologists deserve recognition for going above and beyond to support cannabis patients. Meanwhile, the faculty of pain medicine's stance is at odds with scientific literature reviews which show strong evidence of benefit, and is likewise at odds with the Ministry's approval of cannabis for individual patients with severe chronic pain.

We propose a tender process for training to be provided to specialists, GPs and pharmacists starting from late 2018. This will greatly improve the likelihood of legitimate patients accessing medical cannabis in a timely fashion. Patients shouldn't have to wait for prescriber confidence to build up over a decade or more, which occurred in Israel and Canada and seems to be starting slowly now in Australia.

HELEN'S STORY

In 2004, Helen Kay fell down steps with a refrigerator which landed on top of her. Since then, Helen has struggled with chronic pain in the form of a sensitised central nervous system pain disorder, depression, sleep impairment, parasethesia from nerve damage and bilateral dysdiadochokinesia (impaired motor control in her hands). This all stemmed from a common injury – lumbar disc herniation.

Because of the injury, Helen suffers severe nerve pain and is under the care of a neurologist. As her nerve damage is extensive and progressive, the ongoing loss of function is predicted to result in Helen being confined to a wheelchair.

Nerve pain is one of the conditions with the strongest evidence for therapeutic benefit from cannabis. Through her pain clinic, Helen had tried all the usual suspects – gabapentin, tricyclics, opioids, steroids, benzodiazepines and antidepressants – to little effect, and often with adverse reactions.

Helen first heard about cannabis via the health food movement. She found that juicing raw cannabis into smoothies had excellent results, improving her sleep and her ability to arise well-rested the next morning. From there, Helen progressed to vaporising and topical balms. Using all three methods in conjunction, she found the best pain relief she has ever had for her injury.

Regrettably, in mid-2017, the police raided her property and robbed her of her medicines, as she was cultivating cannabis for her own medical use. With supporting letters from her GP, MRI results and other specialist notes on her condition, the police knew that the use was solely medical, yet they would not let it go. Police have tended to vigorously prosecute patients cultivating cannabis for individual medical purposes.

The court appearance was a revelation. The presiding judge expressed annoyance that such a case was before her and that the police had taken all of the medicine, causing Helen's health to decline further as she resumed her consumption of opioids. The judge was apologetic toward Helen, convicting and discharging her with no penalty. Had Helen been made aware that she could apply for a discharge without conviction, she may well not have ended up with a criminal conviction at all.

A FUNCTIONAL LEGAL FRAMEWORK

Pharmaceutical vs Non-Pharmaceuticals

The previous National government insisted on a pharmaceutical model for cannabis, with Sativex costing $1200 for a three-week supply at retail. Pharmaceutically prepared alternatives still have a similar cost. For example, Canadian producer Tilray has a cannabis oil product which sells for only a 25-33% cost saving in New Zealand when compared to Sativex.

At the other end of the spectrum, some states in the USA would be best described as experiments in progress. The initial 'wild west' phase of an anything-goes market is giving way to improved testing, better product quality and standardisation, and a move towards obtaining GMP status by some producers.

Canada, on the other hand, has been gradually opening up production to products that are not pharmaceutical grade, yet are still made to a high standard. These Canadian products have been repeatedly accepted by the NZ Ministry of Health via the non-pharmaceutical application pathway and are best described as 'near pharmaceutical'. MCANZ believes that these products present the best compromise between product quality and price for the patient. However, the current model for importing products still can nearly double the cost to patients, in comparison to the potential cost of domestic production.

Accessibility of CBD

Because of the very low risk associated with CBD and its derivatives, we propose that low-dose CBD be defined as an over-the-counter, pharmacy-only medicine. We recommend that pharmacies be allowed to sell single-dose products such as capsules with a high ratio of CBD to THC (20:1) or greater, with up to 20mg of CBD per dose. This would bring New Zealand into line with many jurisdictions which sell 10-20mg CBD products as health supplements. By making CBD pharmacy-only, we can keep dispensing within the medical profession, while allowing New Zealanders to access this low-risk product easily for a variety of health complaints. Low-dose products would satisfy a large portion of the market. Doctor supervision could be maintained for those who need higher doses and where specialist support is essential, such as in intractable epilepsy.

Legal Classification of Cannabis

Currently, cannabis-based products are classified as Class B medicines, and prescriptions require Ministerial approval (delegated to the Ministry of Health). Despite the recent changes to allow doctors to prescribe CBD (cannabidiol) without Ministerial approval, CBD still remains a Class B drug alongside more hazardous drugs such as Fentanyl.

In contrast, CBD is treated as an over-the-counter health supplement in other jurisdictions. We propose that all cannabinoids apart from THC and its derivatives be descheduled entirely. They should only be considered for rescheduling should evidence of their harm be produced; currently no such evidence exists. CBD is widely available as a food supplement in other jurisdictions, as it is non-psychoactive and the health risk from taking it is negligible.

Under current law, exemptions from Ministry approval have been carved out, most recently for CBD, but historically for opium and cocaine-derived products. This means "medicinal cocaine" is currently easier to prescribe than cannabis-based products. Schedule 22 of the Misuse of Drugs Act should be amended to remove Minister/Ministry approval for cannabis prescriptions. This would cause cannabis prescriptions to be treated in the same way as other controlled drugs, allowing cannabis to be prescribed by GPs.

78¢ -typical cost per mg of cannabinoids in Sativex in NZ.

19¢ -cost of similar strength oil in Canada from a company committed to research.

10¢ -cost of "Food grade +" oil in Canada and the USA per mg.

PATIENT CARE

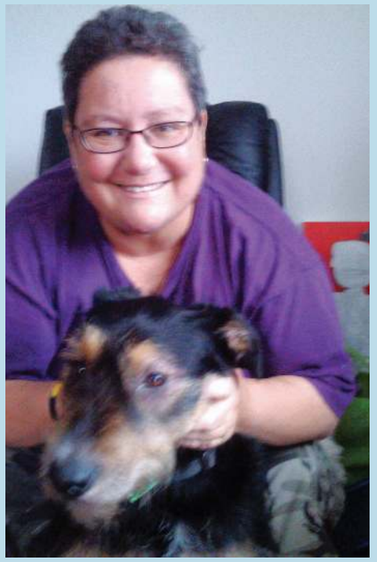
Cannabis as a Medical Specialty

Nearly every jurisdiction where medical cannabis is legal has shown patchy prescribing habits. Often a small portion of prescribers become known as cannabis specialists, and end up prescribing most of the cannabis or granting the most permits to patients. Accepting that this is unavoidable, the law should recognise the fact that there will always be very supportive doctors, and they should be encouraged to cultivate clinical expertise.

We propose that the Ministry of Health define a pseudo-specialty in cannabis-based prescribing, which can be attained by both GPs and specialists. These medical professionals could then run a referral-based business so that other prescribers – who can prescribe cannabis themselves but are not as confident about it – can send their patients to these specialists to trial cannabis-based products. The patient would still remain under the care of their original GP or prescriber. These cannabis specialists would find a suitable cannabis-based treatment for patients, who are then released back to the care of their GP for ongoing care and repeat prescriptions.

This is similar to what already happens for other medications, such as pain clinics initiating methadone treatment for chronic pain patients; the pain specialist helps the patient find a suitable dose and then releases them to ongoing care in the hands of their GP. Co-opting cannabis specialists in this way, while keeping patients under the care of their original medical team, will help prevent doctor-shopping by patients seeking cannabis prescriptions. By defining the specialty, MOH can also encourage the development of excellence in clinical experience, which will become an asset to support product development and clinical trials in New Zealand.

HUHANA'S STORY



Dr Huhana Hickey began her journey with medicinal cannabis over two years ago. At that point, she was on a large cocktail of medicines, and was consuming in the vicinity of 70 different tablets a day. Huhana was frustrated that most of her medical specialists had never heard of the pharmaceutical cannabis product Sativex, despite it being 'on-label' for her secondary progressive MS. Fortunately, after a change in pain specialists, she was successful in obtaining Sativex.

Both Huhana and her pain specialist were shocked to discover that Sativex would cost $1400 a month, with no hope of government funding. Huhana paid for the medication herself for over six months. She had a significant positive response after only two weeks. Due to Huhana being a 'super responder', her daily pill count of other prescribed medicines plummeted to under 10.

Due to the costs, MCANZ assisted Huhana to apply to the Ministry of Health for a cheaper equivalent product. Huhana was the first New Zealand patient approved for a product from the Canadian company Tilray. The Tilray non-pharmaceutical product worked for her.

Unfortunately, Huhana is no longer able to afford either of these products. As a result of her efforts to persevere with legal access to cannabis, she has been left with staggering levels of personal debt. Due to this, Huhana has been gradually ramping up her pill count again. She is trying desperate measures to get funding for legal medical cannabis, such as using the hardship clause to take money out of KiwiSaver. For Huhana, medical cannabis is the difference between being well enough to maintain paid employment, and going on an invalid's benefit.

A LICENSED PRODUCER SYSTEM FOR NEW ZEALAND

The current delivery model for cannabis-based products from overseas is cost-prohibitive for patients. Importing doubles the cost of products in some cases. Overseas companies are not necessarily the profit-driven enemy; it is actually New Zealand pharmacies who have markups of hundreds of dollars on cannabis-based products such as Sativex. Technically, New Zealand-made cannabis products could be dispensed by pharmacies. However, without a mandatory low-markup pricing structure, using pharmacies to dispense cannabis adds another layer of cost that will dis-incentivise patients from choosing legal access.

Another option, currently in use in the US, is the existence of special medical cannabis dispensaries, which are often run by laypeople. This enables maximum access for patients, but provides little clinical oversight.

We recommend instead that the designated cannabis-specialist doctors and their practices have a small but thorough range of cannabis-based products in stock for convenience. This will enable doctors to readily supply patients with small volumes of a wide array of products. Finding the right cannabis product for each patient is still based on trial and error to some extent. The goal is always to strike the right balance for patients between maximal therapeutic effect and minimal side effect, in order to enable patients to go about their daily lives. Striking that balance can involve finding not only the correct dosage level, but also the correct balance of the main cannabinoids (CBD and THC). Furthermore, patients may need to take different doses and cannabinoid combinations at different times of day.

For those patients who have progressed past the trial-and-error phase and are on a regular dose, we propose implementing a delivery model based on the current Canadian licensed producer system, in which the product is delivered directly to the patient.

Licensed Producers

A licensed producer system could work in New Zealand as follows. Prescriptions are sent directly from the prescriber to the licensed producer on a standardised prescribing form with contact details for the patient. The licensed producer, through a web portal, allows the patient to select from a variety of options that meet the prescription (more on this on page 12). Upon payment, the one-month supply is sent directly to the patient via courier. This removes several links in the distribution chain, each with their markup – the manufacturer, the distributor, shipping to the pharmacy and the pharmacy markup. By cutting out the distributor and pharmacy, it is likely that licensed producers will be able to deliver cheaper products to patients.

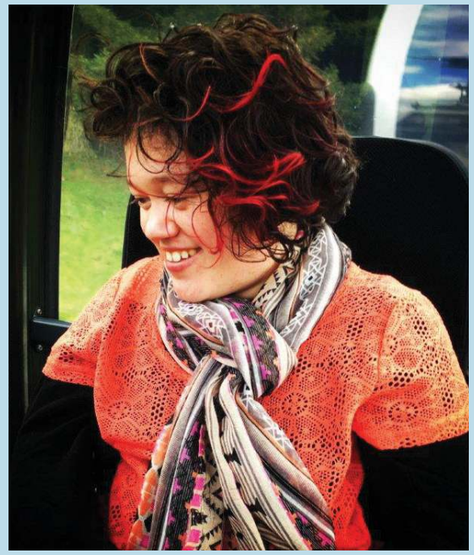
MCANZ proposes vertically integrated (from seed to sale) licensed producers operating in a similar manner to those in Canada. The licensed producer regulations would ensure that producers are held to a high standard, best described as 'near pharmaceutical', to strike a balance between patient costs and product quality. The more inexpensively the product is made, the more likely patients are to pursue legal access, significantly reducing the risk to the current patient pool.

Permits vs Prescriptions

From a medical standpoint, one shortcoming of Canada's law is that patients are granted permits for a quantity of raw cannabis, with no distinction regarding its strength or potency. This makes it difficult to track what strain or strength of cannabis patients are actually using. A patient with a moderate condition such as fibromyalgia may be granted an ounce of cannabis per month, while a severe cancer patient may be granted four ounces a month. Those four ounces can be any potency and any ratio of cannabinoid that the patient chooses. This has invariably led to a market saturated in recreation-oriented cannabis strains, trending towards an ever-increasing potency. We recommend that to ensure therapeutic benefit, doctors prescribe products in a way similar to how conventional medicines are already prescribed.

A prescription system of this type means that prescribers will need to know what treatments are available and how to use cannabis-based products in practice. We believe this will require targeted training by the Ministry of Health contracting out such training.

SARAH'S STORY



Sarah is 24 years old and lives with a condition called Rett syndrome. This congenital neurological disorder impacts every system of the body, with symptoms including seizures; gastrointestinal, autonomic and respiratory dysfunction; dystonia causing muscular contractions; and scoliosis (curvature of the spine). The condition most often becomes apparent anywhere between 9-24 months of age, when acquired skills such as hand use and speech begin to regress, and other symptoms begin to appear.

Sarah was diagnosed comparatively late, at the age of four, although there were strong signs from age two. The condition does not affect her intelligence. Sarah was mainstreamed for primary school, then transitioned to a school with more specialised care. When she was 20, thanks to her mother's fighting for it, she was funded to receive an Eyegaze speech generating device, which allows her to communicate using her eyes, enabling her to express her feelings and describe her clinical symptoms.

Sarah's family pushed for her to trial Sativex as her dystonia and the associated chronic pain escalated. At this stage, pain and palliative specialists had all but given up on trying to alleviate her symptoms. Due to the breathing problems caused by Rett syndrome, opioids were out of the question, and the family successfully campaigned for her to try Sativex.

Sativex has proven very effective for Sarah. The most remarkable effect has been reduced dystonia, which has reduced her pain and led her to regain some controlled movement, leading to an improved quality of life. As icing on the cake, Sarah's epilepsy improved significantly; upon starting Sativex, she went three weeks without a seizure, which was a record for Sarah.

Sarah's family would like to trial other cannabis products. Sativex was not designed for epilepsy, and they would like to trial higher-CBD treatments and different cannabinoid ratios to see if they can improve her quality of life further. The family are in contact with many Rett syndrome families in Canada and the USA, and many of them use cannabis successfully for Rett syndrome. However, individual patients all vary in what products, doses, and methods of administration work best, spurring on the family's desire to trial other products.

Making Raw Cannabis Prescriptions Scientific

Optimal use of cannabis-based products requires individualised prescribing for different medical conditions and different patients. This requires access to varying potencies and cannabinoid (THC/CBD) ratios. CBD and THC each have therapeutic properties which relieve varying symptoms, alone and in combination with each other. CBD can also reduce particular side effects of THC.

We propose developing an easy to understand colour-coding system to denote potencies and cannabinoid ratios for raw cannabis. Doctors would be able to prescribe a raw cannabis as a "potency band", for example, high-THC cannabis for one patient, and more balanced THC/CBD cannabis for another. Licensed producers would ideally supply multiple strains of cannabis which meet each colour category, as more uplifting or sedating strains are preferred by different patients. However, we do not envision that doctors would need to prescribe the specific strain; this can be left to patient choice.

In addition to this classification system, the primary two terpenes for strains consumed would be recorded, allowing consumption patterns to be tracked for further research.

	Pure CBD	HIGH CBD	MILD CBD	BALANCED THC/CBD	MILD THC	HIGH THC
THC:CBD ratio	1:50 or greater	1:50-1:8 ratio	Up to 1:8	2:1-1:2	Up to 8:1	> 8:1
High cannabinoid content (15% cannabinoids or more)						
Low cannabinoid content (less than 15% cannabinoids)						

EXAMPLES:

Canna Sue	White Widow	Harlequin	Purple Orange	Afghan Kush
				

We believe this dosing system would preserve a degree of patient choice, while providing greater transparency than in Canada, where the dried weight is recorded and not much else.

Tracking trends in preferred strains/terpenes over time may yield useful clinical information. Certain conditions may gravitate towards certain chemical profiles, and some side effects may upon review be linked more to specific strain and strength of cannabis.

Example:

Doctor G has a patient with cancer who wishes to use vaporised cannabis for severe neuropathic pain from tumours pressing on the spine and nerve roots. Knowing that the patient wants to remain functional throughout the day but will also need help sleeping through the pain at night, the doctor prescribes 50g of low-potency balanced (yellow) cannabis and 15g of high-THC (black) cannabis per month. This prescription is sent to the licensed producer; the patient then logs into the web portal, where they have the choice of five strains of balanced cannabis. The patient settles on a limonene-dominant strain, "CBD Lemonaid", for its improved flavour. The patient then selects a high-THC strain for its known sedative properties, and settles on "Grand Daddy Purple". This prescribing data and strain selection and profile are loaded onto a database tracking the use of medical patients.

CHARMAINE

Charmaine is a cannabis variety specially bred by a grower who goes by the pseudonym "Bushman Seeds". In spite of its illegal origins, this variety would be an asset to a New Zealand medical cannabis industry. Charmaine is specifically targeted at reducing shaking and muscle cramps from multiple sclerosis. The grower tested over 20 different strains for relieving multiple sclerosis symptoms, and out of that research, Charmaine was deemed the most effective. Charmaine is a project in progress, because the breeder's goal is to breed in good disease resistance so that the plants can be grown outdoors commercially in a temperate climate.

Charmaine was the middle name of the grower's partner. She died in his arms from multiple sclerosis at age 43. Despite having the most rapidly advancing case of multiple sclerosis in New Zealand at that time, she was unable to access Sativex due to resistance in the medical profession. Publicly, the New Zealand Government had declared that Sativex was available for multiple sclerosis sufferers, but all of the specialists and GPs involved in her care were very negative about medical cannabis for MS and refused to prescribe it.

In addition to the scandalous level of care provided to the human Charmaine (Sativex was 'on label' for MS), her partner was prosecuted by police for cultivation. At his trial, the topic of medical cannabis was banned from the courtroom, preventing any discussion of the plight of his partner who was dying. "Bushman Seeds" has been prosecuted several times, with his specially developed plant genetics destroyed by police. Some of these genetics held great potential value for New Zealand patients.

The Licensing Agency

An agency overseen by the Ministry of Health will need to be set up to manage domestic licensed producers. This agency would enact rules and regulations for licensed producers in order to balance product quality and cost, similar to the licensed producer system in Canada. Much of the regulation can be borrowed from other jurisdictions to suit. Canada has embarked on a strong drive to reduce costs as much as practicable, while preserving the safety of the finished products. Some of these products have already been accepted by the Ministry of Health for use in New Zealand, demonstrating their acceptability.

This agency would oversee not only the regulations governing licensed producers, but also personal cultivation by patients.

The regulations governing licensed producers are too comprehensive to cover in detail here. These would cover such areas as site security, product recall processes, testing regimes, pesticide prohibitions and site inspections.

Personnel Requirements

There is significant local expertise around the cultivation of cannabis, and it makes sense for the New Zealand medical cannabis industry to take advantage of that expertise. Naturally, many of those with this experience are saddled with criminal convictions. In contrast to Australia, where personnel requirements for medical cannabis companies rival those of a government security clearance, we propose that employees with cannabis convictions be allowed to participate in the legal industry. Other restrictions around theft, dishonesty offences and gang connections could still be in effect.

Product Testing

Cannabis products would be tested at independent sites to standards defined by MOH, in line with international testing regimes. ESR would need to initially provide the bulk of these services, while over the mid term, other research organisations could also develop analytical testing. Testing requirements can be copied relatively easily from legislation in other jurisdictions.

Testing services currently provided by ESR for hemp are slow and expensive. Testing will need to become available to the patient population via third party testing firms that service the regulatory testing requirements for licensed producers.

Vaporisers

Vaporisers are rapidly taking over from smoking as a form of administration. With Bedrocan making a pharmaceutical grade raw cannabis, and several Canadian companies aspiring to do the same, vaporising is here to stay. The main advantage of smoked or vaporised cannabis is rapid effect, with onset in a matter of minutes.

Vaporisers heat raw cannabis just enough to evaporate the active ingredients without triggering burning. A good vaporiser can reduce the inhalation of harmful substances in smoke by over 90%.

A German company makes the original "Medic" range of vaporisers, which are registered medical devices in some jurisdictions. Several other vaporiser companies are also pursuing higher end devices for medical registration. Currently vaporisers are banned as drug utensils in New Zealand despite their significant harm reduction benefits, MCANZ proposes Vaporisers are excluded from this definition as a matter of urgency.

mini VAP (TM)

MIGHTY MEDIC (TM)

ACCESS TO MEDICINE

Patient Subsidies

Currently, cost is the most significant roadblock to patients staying on the legal pathway to accessing medical cannabis. High product costs are coupled with a lack of government funding. A sickness beneficiary may qualify for funding after a long battle under the "temporary additional support" scheme, which may partially fund Sativex.

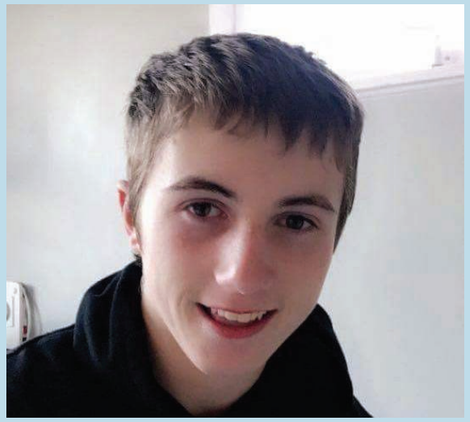
We propose that tax revenues generated by licensed producers are ring-fenced by government for a fund overseen by Pharmac. This fund would be used to fund patients to access medical cannabis in cases where benefit has already been demonstrated by the patient, or where Pharmac is satisfied of the clinical rationale for its use. This fund would work in a similar way to the NPPA, and would allow the neediest patients to have a funding pathway. The amount of Phase 3 trials needed before Pharmac would consider subsidising a medicine in the traditional fashion are likely to be unobtainable for CBP in the near future. Therefore, a new Pharmac funding pathway for patients is needed.

JAKEB'S STORY

Jakeb was born on the 7th March 2003. He was a normal, happy and healthy baby. On the 11th January 2004, Jakeb had his first seizure; he was 10 months old. Within days, his seizures became frequent. On the 30th January, he had his first EEG, which was grossly abnormal. Medication was begun, but Jakeb continued to get progressively worse. He was having up to 300-500 seizures a day.

Jakeb had to wear a helmet to protect his head from injury from repeated falls. Jakeb's seizures were ceaseless and ever-changing, migrating to different areas of his brain. He had multiple seizure types that medicines couldn't control, and in fact medicines aggravated his condition further. These seizures have caused multiple injuries over the years, including broken bones.

Jakeb's development has been frozen in time; mentally he is like an 18-month-old. Jakeb is now 14 years old and has trialled over 15 medications – some twice and even thrice. Jakeb has also had two neurosurgeries. He suffered a stroke and contracted osteomyelitis, a bone infection requiring the removal of a large piece of his skull for 12 months. It has now been thirteen years of seizures, which have harmed him socially, developmentally and physically.



Based on the success of CBD in children with intractable epilepsy, CBD is indicated for Jakeb to trial. His specialist at Starship is prepared to try it. However, the doctor cannot commence an application without the funding for the product being sorted in advance. Due to the high doses of CBD required, ***Jakeb's CBD could cost well over $50,000 a year under New Zealand's current regime for medicinal cannabis imports. The cost could potentially range above $100,000 per year***. In order for Jakeb and others like him to receive this potentially life-changing treatment, someone has to foot the bill, and New Zealand has to find a way to deliver the product more cost-effectively.

LICENSED CULTIVATION BY PATIENTS

While many in political circles may be hesitant, the ability for patients to grow and make their own medicines has been recognised as a basic human right in other jurisdictions. The Canadian Supreme Court ruled in favour of patients' rights in this regard, and the initial Canadian cannabis regime was set up in 2001. Other Western countries have followed suit, including many states of the USA. Some states of Germany are more pragmatic, allowing patients to grow their own cannabis if they exhaust all routes for accessing funding for the expensive pharmaceutical options available. (In a New Zealand context that would mean that if Pharmac does not subsidise the product, the patient would have the right to grow.)

The single greatest benefit of 'grow your own' to patients is cost. Even with a 'near pharmaceutical' regime, the cost can still be several hundred dollars a month. If there is no political will to fund even those low costs (compared to the thousands of dollars that pharmaceutical options cost), then for beneficiaries and ACC claimants, the only realistic option is to grow their own. Thousands of patients are already doing this, so this rather controversial law change would merely be decriminalising what is already happening.

Over the short term, it is unlikely that the cost of cannabis-based products will come down to affordable levels for sickness beneficiaries, and it will take time for licensed producers to build facilities and scale up production. Counter to this, the immediate needs of patients are most rapidly served by allowing them to take matters into their own hands and gardens – and they already do this anyway.

We propose a patient-initiated application scheme to the licensing agency, which would grant a license for personal cultivation, or delegate a license to the patient's chosen compassionate supplier (see below). The Ministry would be granted the power to control a patient home cultivation regime, balancing the need for patient access with public safety concerns. By granting the Ministry power to update the rules, any concerns that arise over time can be dealt with swiftly, rather than resorting to legislative amendments which entail significant delays.

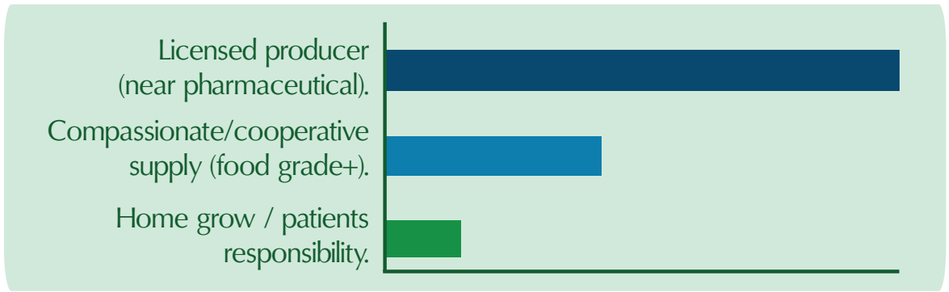
Part of the patient application and licensing process will need to involve harm reduction measures, which has not generally been undertaken well in other jurisdictions. The main health risk from home-grown cannabis is mould contamination. The secondary risks are fire hazards from high output light bulbs and failed cooling systems. Patient education can mitigate these risks.

Only 1 in 20 Canadian patients have applied to grow their own, due in part to the plethora of licensed producers available. Once licensed producers have affordable high quality products, fewer New Zealand patients may seek to grow their own.

COMPASSIONATE SUPPLIERS

Most jurisdictions that allow individual patients to grow also allow communal growing on behalf of several patients, whether that be through a compassionate supplier in a rural location, or a patient cooperative or 'compassion club'. These could also be permitted by the licensing agency. Licenses would be on a per patient basis, with a nominated grower/business/club receiving the permit on behalf of patients. As a holder of multiple permits, this larger scale domestic growing entity would be held to a higher standard than individual home growers, with more vigorous security requirements, training, product control and compliance checks. As approvals for patients will be by the square meter (see next page) this is easily added up for those cultivating for multiple patients.

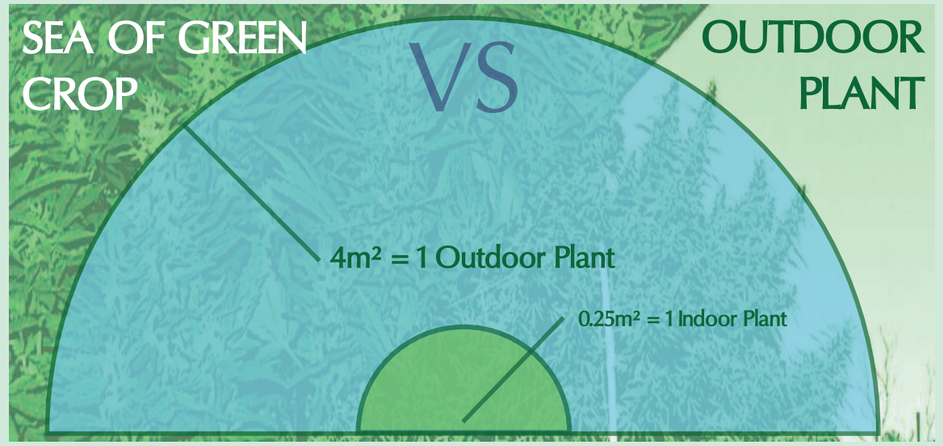
LEVEL OF REGULATORY OVERSIGHT



PLANT LIMITS VS AREA LIMITS

Most jurisdictions choose to limit the amount of cannabis that individual patients can grow. We propose that this be done in terms of total growing area, rather than in terms of the number of plants allowed. Police often boast of seizing dozens of plants, and fail to describe the size of these plants, which can have incredibly small yields in some cases. Growing area, rather than the number of plants, is more directly linked to actual yield.

Differing areas per patient could be granted by the licensing agency in accordance with patient needs, with larger areas allowed for particular medical conditions that need more medicine. By limiting quantities patients can grow the risk of diversion can be minimised, though for most patients this will be an essential medicine they would guard vigorously. Again, such regulations and calculations have already been implemented in other jurisdictions and are easily transferrable.



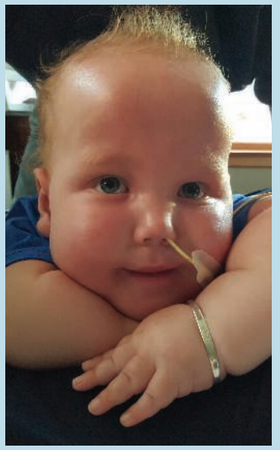
Note: Sea of Green or SOG is an intense cultivation method where plants are packed together very densely to form a uniform canopy, similar to our pine forests but on a tiny scale.

RILEY'S STORY

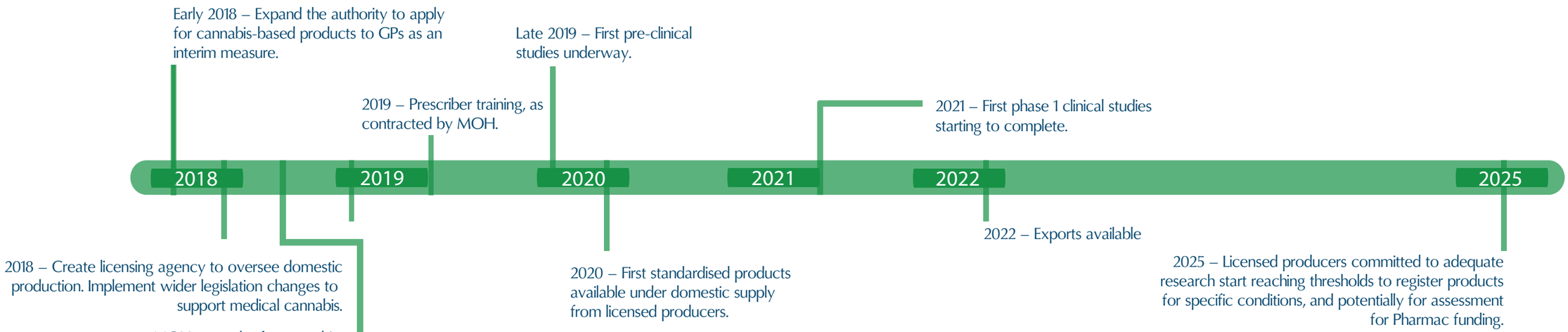
Riley was born with a condition called Zellweger syndrome, which affects one in 50,000 to 100,000 children. Tragically, this condition is terminal. Most children have a life expectancy of one year. Symptoms include seizures and lack of muscle tone, particularly at birth, along with cognitive problems. In Riley's case, seizures were a dominant feature; some nights he averaged a seizure every 10-15 minutes.

There is an outlier with this condition. A young girl named Madeline in the USA started using medical cannabis at the age of six months, and is now the longest surviving Zellweger child ever, at the age of four. Because of the success of Madeline and others with the condition in the USA, Riley's family decided to pursue Sativex, as it was the only legal cannabis product on offer in New Zealand.

Riley's specialists were initially hesitant. Only when another specialist was consulted near Riley's first birthday was an application for Sativex made and granted by MOH. Unfortunately, the process took too long. The Sativex arrived at the hospital, but the doctors opted not to start the treatment until Riley had cleared of a fever. Tragically, the fever claimed his life on the day he was scheduled to start Sativex.



TIMELINE



WHY NOT FOLLOW AUSTRALIA?

Lindsay Carter, an Australian brain tumour and epilepsy patient, was granted the first approval for Schedule 9 botanical medical cannabis products in Australia. Approved products included a cannabis oil and dried cannabis for vaporisation. Lindsay's mother Lanai says it would be a shame if New Zealand follows the Australian model for prescribing and manufacturing medical cannabis.

The Australian system is flawed, with significant issues including delays to access caused by over-regulation. There is a lack of flexibility for patients to receive tailored treatment, access the right medicines, and adjust dosing, formulations and cannabinoid ratios easily. One of the most significant issues is a lack of affordable options for patients. This is putting relief and legal access completely out of reach for the majority of patients in Australia.

Other restrictions and regulatory hurdles meant that Lindsay at one point spent seven months without one of his prescribed products – the dried standardised cannabis for vaporisation. The vaporised cannabis was prescribed for nausea, vomiting, appetite, pain and focal seizures. It is critical for him; without it he cannot maintain his weight. It also helps to stop long focal seizures with speech arrest, which can impact him for up to 2 ¾ hours, and it stops the vomiting he experiences after tonic clonic seizures.

Delays, gaps in supply, unaffordability, and restrictions on products that can currently be imported from Canada are all reasons the Carter family are contemplating moving Lindsay overseas for treatment. The high doses of cannabis were providing significant improvements to his quality of life. Uncontrolled epilepsy and any gap in medicine supply can potentially threaten his life.

A product which may cost $25 overseas may cost approximately $525 per day in Australia to obtain a similar dose of cannabinoids. The oil product which Lindsay needs is not available for import currently. In Australia, a patient like Lindsay would need to consume a whole 1.5 bottles of diluted tincture per day to achieve approximately the dose he could get in just 2 capsules overseas.

The Carter family implores those making

decisions in New Zealand to avoid following Australia entirely.

PATIENTS VS BUSINESS, A CAUTIONARY TALE.

One of the major flaws in Australia's system is the convoluted pathway for patients to gain legal access. Despite this, there has been somewhat of a gold rush and preferential treatment of the business interests of getting cultivation operating in Australia compared to the ease of prescribing. Due to the mismatch between (legal) patient demand and supply there is a poor outlook for many of those companies.

20 ASX Listed companies trying to compete in the Medical Cannabis space.

10 Cultivation licences were issued by the end of August 2017.

300 Patients with legal access by November 2017.

Medical Cannabis Awareness New Zealand (MCANZ) was formed in early 2016 to enable a more coherent voice for patients to be heard on the issue of medical cannabis, and to drive forward legal access. In that time MCANZ has come to dominate the Non Pharmaceutical access scheme, with success in having four alternative products approved on an individual basis, introducing a degree of choice for prescribers and patients in NZ. Our work spans policy, prescriber training, patient advocacy, product research and clinical advice. We aim for a coherent political solution to all aspects of this multifaceted issue for the benefit of the tens of thousands of high needs patients who stand to benefit from access, and who are criminalised currently.

Twitter: @MCAwarenessNZ

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WEB MAGAZINE, ONLINE INFO & FEEDBACK

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For more information on the science behind medical cannabis go to https://mcawarenessnz.org/the-endocannabinoid-system/

To place feedback, send it to: office@mcanz.org.nz