Medical Cannabis Awareness NZ

Submission on Misuse of Drugs (Medicinal Cannabis) Amendment Bill

We ask to speak to our submission by presenting our submission in oral form.

We ask to reserve the right to make a supplementary submission based on the pending release of the draft regulations.

Support of the Bill

1. We support the Bill, as it represents progress towards reducing the criminal status inflicted upon severely ill citizens who are otherwise law-abiding. Unfortunately, with such a complex issue, and the failure of Labour to get any truly independent input, the Bill doesn't go far enough with any of its three main changes.

About MCANZ

2. MCANZ is currently the only registered organisation focused *exclusively* on medical cannabis in New Zealand and has been a registered charity since early 2016.

3. Our focus has been on constructive advocacy in the medical space. In many cases we have been performing a "Guerilla Medsafe" role with the non-pharmaceutical application scheme; we helped patients and their doctors introduce four products for approval via the non-pharmaceutical applications scheme to lower costs and expand treatment options. We represent a large group of patients and supporters who wanted to see the debates of medical and recreational use vigorously separated.

4. MCANZ has a trust structure, a social media presence of nearly 8k supporters, and an internal working database of over 400 severe patients who need legal access as a last resort for their conditions. Due to barriers of cost, and prescriber hesitancy, these patients are poorly served currently.

5. Severe conditions represented in our patient database are extensive, and include conditions such as neurofibromatosis, thalamic pain syndrome, rheumatoid arthritis, Rett syndrome, trigeminal neuralgia, complex regional pain syndrome (CPS), multiple sclerosis, unexplained neurological conditions, cancer survivors, Lennox-Gastaut syndrome and others. We do not represent the interests of those who seek cannabis as a treatment for comparatively mild complaints.

Background: Low numbers with legal access

6. The current regulations and New Zealand's remote geographical isolation have led to possibly the most expensive legal cannabis in the world, in the guise of Sativex. In addition to the exorbitant costs, due to lack of prescriber education there is significant resistance in the medical profession to prescribe Sativex even for on-label uses. For these two reasons alone, our system is a failed one. The bill as it stands does not rapidly address either of these issues.

7. At the time of writing this submission, the best estimate is that approximately 130 patients have legal access to cannabis-based products in New Zealand, with half of those being for CBD. As a comparison, Canada has over 200,000 legal patients; factoring in population differences, this would

be an equivalent of 25,000 legal patients in New Zealand. This would cover a great portion of the 12% of cannabis users who use it mostly or solely for medical purposes.[1]

Background: The abandonment of those with chronic pain

8. Labour promised during the 2017 election to legalise medical cannabis for those with chronic pain. It seems that this was a generous promise that Labour made without much research. This proposal was swiftly axed by the Government, as the definition "chronic pain" does not speak to the intensity of the pain but merely the duration, and would have protected hundreds of thousands of patients from the police. Such a definition would have enabled those with mild conditions, such as people using paracetamol for arthritis, to be covered. It is doubly unfortunate that while deciding to remove this election promise of chronic pain, it does not appear that the Government sought any compromise solution to extend coverage further.

Background: Police don't target the dying

9. It has been our experience that patients who are truly terminal are not prosecuted by the police. We have had much experience with patients and their suppliers being prosecuted, but none of them had 12 months or less to live. For this reason, we feel that the current exemption proposed in the Government's medicinal cannabis bill is toothless window dressing.

10. As was demonstrated by the late Helen Kelly, police don't go after the terminal, but they do go after the severe and permanently disabled. We have had multiple accounts of those prosecuted by police which the public would find abhorrent.[2, 3, 4] This includes semi-regular prosecutions of wheelchair-bound multiple sclerosis patients, and routine prosecution of family members cultivating for their loved ones for significant chronic pain when all other treatments have been exhausted. Others include triple amputees, and an embarrassing raid on a quadriplegic who was suspected of dealing.[5]

Background: Courts are increasingly at odds with police

11. Despite the police stance on prosecuting patients, the courts have often been more lenient. Courts have issued discharges without conviction on multiple occasions[6] for offences ranging from importing two chocolate bars[7], to cultivating up to 62 plants in one case[8]. Many more cases are convicted and then discharged without penalty due to the judge ruling on the side of law while recognising that punitive measures are not in the public interest. For these reasons alone, issuing a statutory defence for cultivation for personal medicinal use isn't a great stretch, but merely empowers the more resistant judges to follow the lead of their more compassionate peers.

Terminal vs. severe or debilitating

12. MCANZ feels that a definition of "severe or debilitating condition" would have been a great compromise for the statutory defence in this bill, as this phrase covers needy patients far more broadly than terminal illness. This phrasing also points to those at the severe end of the spectrum, whom the public has great sympathy for under the current situation. Such a definition would not be open to abuse by people claiming mild chronic pain, who could be served by over-the-counter medications. This change would, however, cover those with severe pain who have ended up on strong opioids or benzodiazepines. It would also cover those who have severe conditions that aren't

[1] Global Drug Survey 2017 https://www.stuff.co.nz/national/health/92677551/global-drug-survey-2017-how-kiwis-are-using-drugs-and-booze

[2] https://www.stuff.co.nz/national/crime/94377637/Man-convicted-of-cultivating-cannabis-for-wifes-chronic-pain

[3] https://www.radionz.co.nz/news/national/119502/home-detention-for-medical-marijuana-campaigner

[4] https://www.stuff.co.nz/national/health/77390698/takaka-womans-use-of-cannabis-to-treat-ms-topical

[5] https://www.stuff.co.nz/auckland/91117249/mother-in-panic-attack-over-tetraplegic-sons-missingcarers

[6] https://www.odt.co.nz/news/national/oamaru-man-94-was-sent-dope-post

[7] https://www.stuff.co.nz/national/health/77438549/golden-bay-woman-wins-legal-victory-for-medicinal-cannabis

[8] http://www.stuff.co.nz/national/6651801/Activist-gets-off-cannabis-charges

directly related to chronic pain, such as those with severe Crohn's disease, who can have excellent results (despite the paucity of phased clinical research); multiple sclerosis; and even Tourette syndrome.

- Recommendation 1. Alter protections from those certified as having "terminal" to those with "severe or debilitating" conditions.

- Recommendation 2. Alter the protections to include the offences of manufacturing cannabis preparations, and of cultivation, if courts/police are satisfied it is for the sole purpose of personal medical use.

- Recommendation 3. Extend these defence provisions to caregivers when the police/courts are satisfied that offences are solely for the benefit of a patient with severe or debilitating conditions.

Cannabidiol and the alphabet soup of cannabinoids

13. On another change proposed in the legislation, around the descheduling of cannabidiol (CBD): While we support this move, it is in effect a minor change with no front-end results for patients seeking access, who have already been served by the regulatory exemption of the previous government. MCANZ feels that changing the legislation for one cannabis compound is a missed opportunity.

14. There are a raft of other cannabinoid compounds that also hold therapeutic benefit and no psychotropic effects, which should also be descheduled. For example, GW Pharmaceuticals is developing a cannabidivarin (CBDV) extract as an alternative to cannabidiol.[9] Other cannabinoid isolates have been developed in the United States, such as those from Mary's Medicinals, which feature a cannabichromene (CBC) topical[10]; a few nutritional supplement makers are already using cannabigerol (CBG)[11]. Finally, there is tetrahydrocannabivarin (THCV), which in preclinical studies has shown positive effects on insulin control and is being researched as a treatment in the prevention of diabetes.[12] The only known strongly psychotropic compounds are tetrahydrocannabinol (THC) and its degraded and powerfully sedative form cannabinol (CBN).[13]

15. MCANZ proposes that cannabinoids are split into two categories: those with known strongly psychotropic properties (and therefore a potential for abuse), and those with little to no known psychotropic effects. This latter group should be descheduled. This would enable a raft of emerging medicines to be classified appropriately. This would avoid the need to revisit this legislation on an ongoing basis as these medicines become available (a similar but inverse experience of the constant banning of new compounds in the days prior to passage of the Psychoactive Substances Act). Such revisiting of the legislation would be a gross waste of resources and could be decisively dealt to with an amendment to this legislation so that these benign compounds are not scheduled, rather than continuing to enshrine an unscientific classification of cannabinoid compounds left over from the 1970s. Our mantra on this point is *"do it once, do it right"*.

- Recommendation 4. Deschedule 98%-pure forms of all major non-psychoactive cannabinoid compounds alongside CBD, including CBC, CBDV and CBG.

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[9] https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-plc-announces-us-patent-allowance-use-cannabidivarin-cbdv-treating

[10] http://www.marysmedicinals.com/products-properties/

[11] https://bluebirdbotanicals.com/new-product-92-cannabigerol-cbg-isolate/

[12] http://care.diabetesjournals.org/content/39/10/1777

[13] https://www.steephill.com/blogs/34/Cannabinol-(CBD):-A-Sleeping-Synergy

Cannabis ratios and scheduling

16. Cannabis products are complex, and are typically defined by ratios of cannabinoids that directly affect their psychoactivity. In Annex A, we propose classifying products in bands based on the THC:CBD ratio, which broadly matches their therapeutic properties, as well as their potential for abuse. This classification could stretch to the scheduling, and would also signal to prescribers the relative safety profiles of the varied products. We propose that high-THC preparations remain class B, while balanced products like Sativex and its equivalents are classified as Class C to denote their much-reduced risk. See Annex B for a visual guide explaining the spectrum of effects.

    - Recommendation 5. Reschedule balanced (2:1 THC:CBD or less) cannabis preparations as Class C.

The shape of the regulations

17. It is difficult to submit in support or against the regulation-enabling provision without knowing the intent of the regulations. However, we can speak to how we would like things to be shaped. We ask for the right to make a supplementary submission on these regulations once released. MCANZ has included as a reference our policy booklet (Annex A). In a vacuum of knowledge around the regulations, we would like the regulations to match our policy booklet as much as possible. Some of the key points are laid out below.

Canada or bust

18. We feel that the best model to follow is Canada, which has many profitable vertically integrated (from seed to sale) licensed producers of medical cannabis, with products made to a high standard. For the top tier producers, we term the quality "near-pharmaceutical". Indeed, one of the companies we had initial success with getting introduced into New Zealand has transitioned to pharmaceutical development, and the other company we have had patients approved for is having an inspection for certification to certify their products as pharmaceutical quality. There are small flaws in the Canadian model that can be improved upon, which we have put forward in our policy booklet, attached as Annex A.

Near-pharmaceutical standards for manufacture

19. Canada's standards of manufacture are called Good Production Practices (GPP). Several of these products from different manufacturers have already been approved for individual patients in New Zealand. These products are very close to pharmaceutical quality. We would argue that due to these products already being accepted, that any regulations should be no more restrictive than those that were used to manufacture the products in question. Setting this standard for manufactured products should ensure the trust of prescribers, and lead to the cost of products tumbling. See Annex C for a visual representation of cost versus product standards and what is broadly possible.

    - Recommendation 6. Set standards for manufacture that are similar to those in use in Canada under the GPP scheme.

Products vs. permits

20. Canada has worked to a permit system which enables patients a large degree of choice. This has invariably led to some manufacturers focusing on the most psychotropic varieties available.[14] We would propose that cannabis remains in the realm of prescribed products; however, rather than prescribing a specific preparation, the doctor would prescribe a category or "cannabinoid potency and ratio" band as explained in Annex A. This would ensure that prescribers can comfortably

[14] https://www.tilray.ca/en/products/?

prescribe a strength of product (primarily raw cannabis), without having to know the names of individual cannabis strains, which take myriad forms. If we are to have multiple manufacturers with varied strains of cannabis this is especially important. Through doctors prescribing a product band, patients do have a degree of choice within that band, as the taste of the product and its more minor sedative or energising properties are a patient-driven choice. Some strains taste like potpourri, while others have a pleasant lemon scent when vaporised. Failure to give patients a degree of choice in products will result in continuation of the illicit status quo. This concept of product bands, while innovative, is already done voluntarily by various companies in Canada, each with their own classification systems. Regulating this at a national level would have significant benefits for ease of prescribing, and with a robust domestic industry would be a strong incentive for patients to transition to a legal market.

Figure A: A proposed color-coded classification scheme for prescribing, as outlined in Annex A.

- Recommendation 7. Set up a product band system based on cannabinoid ratio and potency for prescribing products.

Prescribing barriers

21. The government has indicated that it will be setting up a working group to discuss prescribing barriers and whether it is still appropriate to have Ministry of Health input in the process. Considering the exemptions that have been made historically to prescribe opium tinctures and cocaine-based preparations without Ministry intervention[15, 16], we feel that a working group is a stalling tactic on this point. To treat cannabis equitably with other medications including medicinal cocaine, we suggest that cannabis-based preparations are added to Schedule 22 of the Misuse of Drugs Regulations as soon as practicable.

- Recommendation 8. Immediately amend Schedule 22 of the MODR so that GPs can prescribe cannabis-based preparations freely.

Nurse practitioners

22. MCANZ also feels that due to the benign safety profile of cannabis-based medicines[17], that other practitioners should also be able to prescribe cannabis-based products in limited circumstances. In

[15] http://www.bmj.com/sites/default/files/response_attachments/2015/03/Medicinal%20Cannabis%20The%20Evidence%20V1.pdf

[16] http://www.legislation.govt.nz/regulation/public/1977/0037/30.0/DLM55371.html

[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2413308/

particular, MCANZ would like to see nurse practitioners be able to prescribe in end-of-life care. Due to the present lack of formal training on medical cannabis, we recommend that this be a credentialed activity requiring formal training on medical cannabis first. This also greatly increases the chance of patients having legal access for their end-of-life care.

- Recommendation 9. Implement a credentialed process for nurse practitioners to be able to prescribe cannabis-based products in end-of-life care as a minimum.

Pharmacy-only medicines

23. In many jurisdictions, CBD is an over-the-counter health food supplement.[18] Due to its abuse/risk profile of approximately nothing[19], we propose a compromise where low-dose high-CBD medicines are classified as over-the-counter, pharmacy-only medicines, so that patients may have the greatest access to those products with the least risk. This would enhance the viability of a New Zealand industry and promote patient safety, as the most rapid uptake would likely be for the low-risk products available at pharmacies.

- Recommendation 10. Make low-dose high-CBD products (with a THC:CBD ratio of 1:20 or higher) available as over-the-counter, pharmacy-only medicines.

Vaporisers: Ditch the classification as drug utensils

24. Vaporisers significantly reduce the harms associated with inhaled cannabis. Some of the top-end models virtually eliminate the inhalation of carcinogens.[20] For this reason, MCANZ proposes that vaporisers be stripped of their drug paraphernalia status. While this is beyond the current scope of the Bill and could apply to both medical and recreational uses, now is the perfect opportunity to amend the legislation for significantly better public health outcomes.

- Recommendation 11. Legalise vaporisers by exempting them from the “drug utensils” offences.

Medical training

25. Due to the lack of knowledge in the medical profession – where the typical medicinal cannabis activist is more informed of the emerging clinical evidence than the typical medical professional – we propose that the MOH puts to tender some training packages to be held around the country as 1-2 day workshops for doctors. This would ensure that GPs and specialists are up to speed with emerging evidence, the clinical positioning of cannabis in other more mature jurisdictions, and potential risks in the medical product space.

- Recommendation 12. MOH to tender for providing medical cannabis training, to jump-start prescriber confidence and competency.

Funding cannabis-based medicines

26. Cannabis-based products are unlikely to be funded by PHARMAC in the foreseeable future, even with good evidence. Additionally, the PHARMAC NPPA scheme, through which patients can apply for individual funding for unfunded medicines, refuses to take into account demonstrated benefits to the individual. In one case this meant that a patient with an incredibly positive response to Sativex for Tourette’s was declined individual funding, citing lack of published evidence of efficacy, despite

[18] https://www.cbdoilsuk.com/

[19] http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf

[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4718604/

the demonstrated efficacy for the patient. That patient went on to have a case study trial implemented to receive DHB funding instead.[21]

27. MCANZ feels a cost-neutral pathway to funding products for patients is preferred, considering ongoing budgetary pressures on the government. A potential solution to this is that *new* tax revenue generated from the licensed producers could be ring-fenced for its own funding scheme overseen by PHARMAC, with altered criteria taking into account patient success if attested by specialists. This would enable funding for legal treatments for those with severe conditions such as Dravet, Rett and Lennox-Gastaut syndromes, among others.

    - Recommendation 13. Tax revenues from licensed producers to be set aside for a cannabis-specific funding scheme administered in the spirit of PHARMAC's NPPA scheme.

Patient licensed cultivation

28. MCANZ feels that in the mid-term, while licensed producers are setting up, a regime should be in place to license individual patients to self-supply in limited circumstances. Due to the reluctance of doctors to prescribe cannabis-based products currently, and the fact that permitting patients to grow controlled drugs is outside of what could reasonably be considered doctors' scope of practice, we propose that patients should be able to apply to the licensing agency, as the large licensed producers would. Criteria for assessment would involve clinical efficacy, ethical concerns and background checks, so that cultivation would be tightly controlled as a privilege for patients in need, with visibility for health officials.

    - Recommendation 14. Enable the proposed licensing agency to license individual patient cultivation on a restricted, controlled basis.

Beyond the Bill: Medical Cannabis in Aotearoa: A Comprehensive Solution for 2018 and Beyond

29. With the lack of draft regulations to make comment on, we propose that the select committee review our policy booklet, *Medical Cannabis in Aotearoa: A Comprehensive Solution for 2018 and Beyond* (Annex A), as a reference on where we think regulations should be headed. Taking into consideration the success of Canada's production regime and the alteration from permits to products as described in Annex A, our well-researched policy has many more points beyond what is covered in the Bill.

    - Recommendation 15. Enact the preferred policy of MCANZ in its entirety, as laid out in *Medical Cannabis in Aotearoa: A Comprehensive Solution for 2018 and Beyond.*

For your consideration,

Shane Le Brun on behalf of Medical Cannabis Awareness New Zealand (MCANZ) Registered Charity CC52960

[21] http://www.nzherald.co.nz/bay-of-plenty-times/news/article.cfm?c_id=1503343&objectid=11772432