Submission on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill

This submission is from the National Organisation for the Reform of Marijuana Laws (NORML New Zealand Inc).

Summary of Recommendations

1.	We support a new law for medicinal cannabis and advocate a "dual access" approach of pharmaceutical-grade products for doctors to prescribe, and cannabis-based products available as herbal remedies either through self-provision (including caregivers), or from local craft producers.
2.	Provide appropriate support and resourcing to make the new legislation and regulations workable.
3.	Fund ongoing research, both specifically for medicinal cannabis products, use, prescribing / physician education, patient access, etc.; and separately for an evaluation (see section S8, below) of the impact of the legislation and regulations at future points.
4.	De-schedule CBD and implement a "dual access" approach of pharmaceutical versions available as prescription medicines (like Australia) and lower-strength CBD health supplements available over the counter (like in the USA, Canada and in Europe).
5.	Allow a wider tolerance of other cannabinoids in CBD products, for example 5%, which would allow 1:20 ratio products commonly available overseas and would allow for more straightforward domestic production of CBD.
6.	Provide a pathway for CBD and other cannabis-based products to be manufactured in New Zealand. Amend the hemp regulations and/or amend s14 of MoDA 1975 to allow licences to be issued for making products for consumption.
7.	New standards for medicinal cannabis products should include both food-grade and pharmaceutical-grade to allow for different sets of patient needs. Take a herbal remedy or food-based approach for non-pharmaceutical cannabis products, which will allow local and affordable products to be available in New Zealand more quickly and cheaply.
8.	Support a compassionate approach which exempts legitimate patients from prosecution. Do not limit it to terminal patients.
9.	Expand the exemption so any caregiver designated by the patient can, like the patient, possess a legal certificate which would exempt the caregiver from prosecution. This can be achieved by adding a Clause 5 (2C): "has a certificate stating that the patient has designated this person as their caregiver for the purposes of obtaining cannabis".
10.	Tackle affordability by allowing self-provision of natural forms of cannabis, which is common overseas. Insert the word 'cultivates' to Clauses 5 (2A) to make it clear that the patient or caregiver can cultivate their medicinal cannabis.
11.	Replace the term 'terminal illness' in the exemption with the phrase 'terminal illness or chronic and debilitating medical condition, where a doctor has recommended the use of cannabis'.
12.	Strengthen the protection given in Clause 5 (3A) by providing a mechanism for patients and caregivers to submit their documentation prior to being taken to court.
13.	Support the exemption for utensils and extend it to equipment used to cultivate or manufacture medicinal cannabis.

14. Support the focus on safety and quality for medicinal cannabis products – with more emphasis on affordability.
15. Encourage Craft Cannabis, not just Big Cannabis. New regulations should not become a *de facto* prohibition, locking out local producers.
16. Medicinal cannabis balms, tinctures, juices, or smoothies should be treated as herbal remedies.
17. Workers with cannabis convictions should not be prohibited from entering the industry.
18. The review of this legislation should be appropriately supported, resourced, and evidence-informed.
19. The review should examine cases where seriously and chronically ill patients, acknowledged as such by their physicians, have suffered legal interdiction as a consequence of their use of cannabis for medicinal purposes.
20. The review should be carried out independently of the Ministry of Health; patients, whānau and providers should be represented; professionals known to be hostile towards the medicinal use of cannabis should be avoided; and the broader societal impact of the legislation should also be considered.

Note: We would like to appear in person to address this submission. We ask to reserve the right to make supplementary submissions based on any matters arising including the drafting of related regulations.

Commentary

GENERAL PRINCIPLES

1. We support a new law for medicinal cannabis. Like most New Zealanders, we find it intolerable that people with medical conditions which could benefit from the use of medicinal cannabis products are denied that choice or forced to act illegally to obtain those benefits. This unacceptable situation was highlighted in 2016 when Helen Kelly went public with her use of medicinal cannabis for terminal cancer and her unreserved support for medicinal cannabis to be made more readily available. Her campaign for medicinal cannabis was a significant push toward the development of this Bill we are submitting on.

2. We strongly support the Government's stated intention to create a Medicinal Cannabis Access Scheme, which this Bill is a part of. However, we are concerned it will be a corporate pharmaceutical-style scheme like Australia. We urge a more compassionate regime that also allows small-scale "craft cannabis" production and for patients to provide for themselves, such as in Canada and many US states.

3. We support the principles underpinning this Bill, stated in the explanatory note of the Bill and during the first reading[1], calling for "fairness, quality and safety, and compassion". While this Bill provides some elements of these, the principles of fairness and compassion are significantly under-emphasised. A truly patient-focused approach should go much further.

What would Helen Kelly want?

4. We strongly believe the test of any new law should be to ask, "What would Helen Kelly want?" Helen was an outstanding champion of patients' rights and of the effectiveness of simple, self-made cannabis oils and balms. She was advocating not for expensive pharmaceutical-grade cannabis products but for herbal tinctures and balms that can be easily and cheaply made by anyone.

5. This Government said it would "legalise medicinal cannabis"[2]. We think most people understand that to include real botanical cannabis that is grown by the patient or their caregiver, not just pharmaceutical derivatives. According to UMR polling that NORML conducted with Helen Kelly in 2016[3], 76 per cent of New Zealanders agreed when asked *"Should Parliament change the laws of New Zealand so that patients have safe legal access to affordable medicinal cannabis and cannabis products when prescribed by a licensed doctor?"* Almost 4 out of 5 supporters of a strict approach that requires a doctor's prescription would also support having medicinal cannabis sold as a herbal remedy.[4]

6. NORML advocates a "dual access" approach of encouraging the development of pharmaceutical or near-pharmaceutical-grade products so doctors can feel comfortable prescribing them within the conventional system, while also providing access to cannabis-based products made as herbal remedies (to a food-grade standard), either through self-provision or by caregivers, or from local craft producers.

[1] https://www.parliament.nz/en/pb/hansard-debates/rhr/combined/HansDeb_20180130_20180130_24
[2] http://www.labour.org.nz/100days
[3] https://norml.org.nz/umr-poll-overwhelming-support-for-medical-cannabis-law-change/
[4] https://app.box.com/s/xic5vblysm9dys16uecusypzumn2d6t1

Making good medicinal cannabis law

7. NORML has advocated for sensible cannabis law reform since 1980. Based on extensive consultation with members, patients and advocates including Helen Kelly, NORML has adopted a 4-Point Model[5]:
    a. **Patient focused: safe affordable access to botanical cannabis.** Reforms must be meaningful. Putting the needs of patients first means a system where patients are safe, legal, and can access natural (botanical) cannabis, not only pharma products. Affordability is a huge barrier for patient access. The current process is also complicated and confusing and needs to be simplified for both patients and prescribers.
    b. **Immediate effect (not just a long-term development pathway).** One in twenty New Zealanders now uses cannabis medicinally, according to the Ministry of Health. Many are severely ill with life-threatening conditions. These patients will not be helped with a drawn-out development pathway (as in Australia). Patients need an accelerated process that allows immediate access – perhaps an interim period so products can be brought to market, and/or an exemption for self-provision.
    c. **Domestic production: via licensed providers, including small scale providers (families & individuals).** The prohibition on domestic manufacture should be repealed. Producing cannabis-based products in New Zealand will bring down costs to patients (which are largely due to unreasonable pharma-grade standards, regulatory requirements in other counties, strict import controls, significant retail mark-up, and so on). Domestic production would create jobs and potential export revenues. Small scale providers (including families and individuals) should have an easier pathway to being licensed, similar to a driver's licence or firearms licence.
    d. **Self-provision: choice to grow your own as a herbal remedy.** We think most people consider "legalise medical cannabis" to mean natural botanical cannabis, including self-provision. Patients and doctors need choices, not just pharmaceutical products but also herbal remedies. This is what Helen Kelly wanted. Self-provision means it can be cheap, quick, natural, and not from gangs.

International experience

8. Substantial international experience in allowing medicinal cannabis has shown that legislation can be successfully enacted to provide access to genuine patients without substantial adverse effect. In the Netherlands, Germany and much of Europe, patients can access herbal cannabis (Bedrocan®) from pharmacies. Canadian patients can access herbal cannabis at either food-grade or pharma-grade from local dispensaries and Licensed Producers, or can choose to grow their own. Over 200 million Americans can obtain medicinal cannabis from dispensaries and in many states can choose to grow their own or have a caregiver grow it for them.

9. Research shows this has not been associated with increased rates of use – for example amongst teens[6], although where negative impacts from medicinal cannabis schemes are observed these may be mediated by appropriate regulation[7]. Reports from the US have shown conflicting results for road

[5] https://norml.org.nz/medical/patient-focused-medicinal-cannabis-normls-4-point-model-for-law-reform/

[6] Hasin, D. S., Wall, M., Keyes, K. M., Cerdá, M., Schulenberg, J., O'Malley, P. M., ... & Feng, T. (2015). Medical marijuana laws and adolescent marijuana use in the USA from 1991 to 2014: results from annual, repeated cross-sectional surveys. *The Lancet Psychiatry*, *2*(7), 601-608.

[7] Pacula, R. L., Powell, D., Heaton, P., & Sevigny, E. L. (2013). *Assessing the effects of medical marijuana laws on marijuana and alcohol use: The devil is in the details* (No. w19302). National Bureau of Economic Research.

deaths (signalling the importance of on-going research)[8] [9], lower rates of crime, particularly violent crime[10], suicide[11], and opioid fatality[12] and use[13].

10. We are concerned that briefing papers released by the Ministry of Health[19] appear to show a strong focus on copying Australia almost from the beginning. We question why approaches taken in other jurisdictions, for example, as outlined for Canada by Ko and colleagues (pages 738-9)[20] or the longer-established Dutch medicinal cannabis programme[21], have not received the same level of attention, given well-publicised criticisms in Australia that their approach has not produced significant benefits for patients. An analysis of currently existing regulatory regimes is included in Appendix 1[22].

Resourcing to make it work

11. Irrespective of its content, if the Bill is passed the resulting legislation and regulations will require appropriate support and resourcing to make them workable. Therefore, careful consideration should be given to the needs of resulting legislation and regulations during the Bill's discussion. The Psychoactive Substances Act (PSA) 2013 provides an example of how under-resourcing might negatively impact on well-intended legislation. Notwithstanding the politics negatively impacting the PSA 2013, its efficacy as viable legislation was further undermined by the limited resourcing (including personnel) available within the Ministry of Health (MoH) at the time of its drafting, and by the limited support available for the resultant Psychoactive Active Substances Regulatory Authority[23].

12. To ensure the viability of resultant legislation, serious consideration should also be given to funding on-going research, both specifically for medicinal cannabis products, use, prescribing / physician education, patient access etc.; and separately for an evaluation (see section S8, below) of the impact of the legislation and regulations at some future point (possibly several, e.g. at one, three and five years post-implementation). Funding (approximately $500,000 annually) dedicated to the broad area of drug policy was previously available under the MoH's National Drug Policy "Discretionary Fund", implemented by then Associate Health Minister Jim Anderton in 2004, but subsequently dropped by the fifth National Government during its first term (circ. 2009). Historically, drug use research has been underfunded in New Zealand, particularly where it focuses specifically on policy rather than on the negative impact of drug use *per se*.

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[8] Mark Anderson, D., Hansen, B., & Rees, D. I. (2013). Medical marijuana laws, traffic fatalities, and alcohol consumption. *The Journal of Law and Economics*, *56*(2), 333-369.

[9] Salomonsen-Sautel, S., Min, S. J., Sakai, J. T., Thurstone, C., & Hopfer, C. (2014). Trends in fatal motor vehicle crashes before and after marijuana commercialization in Colorado. *Drug & Alcohol Dependence*, *140*, 137-144.

[10] Morris, R. G., TenEyck, M., Barnes, J. C., & Kovandzic, T. V. (2014). The effect of medical marijuana laws on crime: evidence from state panel data, 1990-2006. *PloS one*, *9*(3), e92816.

[11] Anderson, D. M., Rees, D. I., & Sabia, J. J. (2014). Medical marijuana laws and suicides by gender and age. *American journal of public health*, *104*(12), 2369-2376.

[12] Bachhuber, M. A., Saloner, B., Cunningham, C. O., & Barry, C. L. (2014). Medical cannabis laws and opioid analgesic overdose mortality in the United States, 1999-2010. *JAMA internal medicine*, *174*(10), 1668-1673.

[13] Boehnke, K. F., Litinas, E., & Clauw, D. J. (2016). Medical cannabis use is associated with decreased opiate medication use in a retrospective cross-sectional survey of patients with chronic pain. *The Journal of Pain*, *17*(6), 739-744.

[19] Ministry of Health: Advice on the Government's Medicinal Cannabis 100-day Commitment https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/misuse-drugs-medicinal-cannabis-amendment-bill/advice-governments-medicinal-cannabis-100-day-commitment

[20] Ko, G. D., Bober, S. L., Mindra, S., & Moreau, J. M. (2016). Medical cannabis–the Canadian perspective. *Journal of pain research*, *9*, 735.

[21] See http://www.ncsm.nl/english/the-dutch-medicinal-cannabis-program

[22] Belackova, V., Shanahan, M., & Ritter, A. (2017). Mapping regulatory models for medicinal cannabis: a matrix of options. *Australian Health Review*.

[23] https://www.drugfoundation.org.nz/matters-of-substance/november-2014/our-psycho-psychoactive-legislation/

Response to claims made about the Bill

13. During the First Readings of this Bill and Chloe Swarbrick's Members Bill on the same subject, we tracked comments made by MPs in the House to gauge their knowledge about medicinal cannabis. We discovered several commonly held misperceptions which were voiced by multiple MPs. Some of these opinions were voiced by members of the Health Select Committee. In the spirit of education, these common misconceptions and information to counter the misconceptions are given in the table below.

Common misconception	**Reality**
CBD is the medicinal component of cannabis. THC is psychoactive and is not medicinal.	Both CBD and THC are medicinal compounds, with differing medicinal uses and different effects. Depending on the medical condition, different patients need each of these compounds; some need either CBD or THC, and some need a combination of the two in varying ratios. CBD and THC are not interchangeable; a patient who needs THC may not benefit from CBD.
Cannabis can cause mental illness, particularly psychosis.	This claim has been scientifically disproven. A recent scientific meta-analysis of all research on the topic confirmed that there is no direct link between cannabis and psychosis. Rather, previously reported links between cannabis and psychosis were actually due to the use of multiple illegal drugs in combination.[24]
A liberal medicinal cannabis regime will cause harm to youth, by encouraging more cannabis use by young people.	Jurisdictions which have legalised medicinal cannabis overseas have shown no increase in youth cannabis use, in numerous academic studies.[25]
Cannabis must be treated like any other medical preparation, with pharmaceutical-style prescriptions and dosing.	Although some extreme medical conditions do require precise dosing, most medicinal cannabis users tell us they are happy to self-titrate using herbal products, including raw cannabis, balms and oils. Medicinal cannabis regimes in the US and Canada simply permit patients to possess a certain amount of cannabis and consume it as needed, rather than a doctor stipulating the exact dosage. Cannabis has an excellent safety profile compared to many pharmaceutical medications. Negative health effects of long-term cannabis use have been shown to be minimal in a longitudinal New Zealand study.[26] Even long-term heavy smoking of cannabis has been shown not to cause lung cancer.[27] There is no evidence that anyone has ever died of overdose from cannabis.
There is not enough scientific research.	In fact, there is an abundance of scientific research on the benefits of medicinal cannabis. A recent exhaustive survey of all scientific literature

[24] Mark Shevlin, Eoin McElroy, Jamie Murphy, Philip Hyland, Frédérique Vallieres, Ask Elklit, Mogens Christoffersen, (2017) "Cannabis and psychosis: the impact of polydrug use", Drugs and Alcohol Today, Vol. 17 Issue 3, pp.186-194, https://doi.org/10.1108/DAT-03-2017-0014

[25] Full list of scientific references available at "Study: No Increase In Problematic Cannabis Use By Young People Following Changes In Marijuana's Legal Status", http://blog.norml.org/2017/07/11/study-no-increase-in-problematic-cannabis-use-by-young-people-following-changes-in-marijuanas-legal-status/

[26] Oaklander, Mandy. "Long-Term Pot Smoking Doesn't Seem to Harm Health: Study", *Time*, 7 June 2016, http://time.com/4359757/pot-smoking-marijuana-cannabis-health/

[27] Kaufman, Marc. "Study Finds No Cancer-Marijuana Connection." *Washington Post*, 26 May 2006.

	by the US National Academies of Sciences, Engineering and Medicine found the strongest evidence of therapeutic benefit to be for chronic pain, chemotherapy-induced nausea and vomiting, and multiple sclerosis. The study also found evidence of therapeutic benefit for a long list of other conditions.[28]

CLAUSE BY CLAUSE ANALYSIS

S4: De-scheduling Cannabidiol (CBD)

14. This clause amends s2 of MoDA 1975 (Interpretations), to effectively de-schedule cannabidiol (CBD). CBD is a non-psychoactive cannabinoid found in cannabis plants that is indicated to help patients with a wide variety of conditions including epilepsy, arthritis, cardiovascular disease, cancer, diabetes, gastrointestinal disorders, multiple sclerosis, PTSD, antibiotic-resistant infections, anxiety and other mental health disorders, and more. CBD can be made from legal hemp crops and is available in many countries.

15. Despite not being listed in the Misuse of Drugs Act, the NZ Ministry of Health says CBD is currently a Class B1 controlled drug that has, until September 2017, required special Ministerial approval under the 1977 Misuse of Drugs regulations. In November 2017, the WHO Expert Committee on Drug Dependence (ECDD) [29] concluded that, in its pure state, cannabidiol does not appear to have abuse potential or cause harm. As such, CBD is not considered a scheduled substance (only as a component of cannabis extracts).

16. We support CBD not being a controlled drug – as per the recent recommendation from the World Health Organisation. De-scheduling CBD will mean it is no longer subject to overly strict international controls, including for production and supply. However given CBD is non-psychoactive, non-addictive and appears to be non-toxic we question whether it should be prescription-only medicine. We recommend a "dual access" approach of pharmaceutical versions being available as a prescription medicine (like Australia) and over the counter as a health supplement like in the USA, Canada and in Europe.

17. We support having a tolerance for trace amounts of other cannabinoids, as this means that botanically-sourced (i.e. natural) cannabis can be used rather than having to make CBD in a laboratory. We understand however that it is still very difficult to achieve the proposed 50:1 ratio. We recommend a wider tolerance of other cannabinoids, for example 5%, which would allow 1:20 products commonly available overseas and for more straightforward domestic production. We note the proposed 2%, although the same as existing regulations, appears to be copied from Australia which we in turn understand reflects the product formulation for a proprietary product called *Epidiolex*®, from the manufacturers of *Sativex*®. We note *Epidiolex*® is at least twice the price of *Sativex*® – well out of reach of most patients – whereas CBD made from hemp at a food-grade level is widely and cheaply available overseas.

18. Under the proposed Bill it will remain very difficult to produce CBD products in New Zealand, or to register any CBD products as approved medicines. The Ministry of Health has taken the position that

[28] US National Academies of Sciences, Engineering and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, 12 Jan 2017, http://nationalacademies.org/hmd/Reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx

[29] *Cannabidiol (CBD) Pre-Review report* (agenda Item 5.2); World Health Organisation Expert Committee on Drug Dependence; http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf

hemp licences cannot be used to produce medicines and says a MoDA s14 controlled drugs licence must be obtained to produce it. However, a controlled drug licence can only be used to produce drugs for research or study, not commercial purposes such as producing a medicine. A new pathway for approval to CBD based products will be necessary. It seems to us it would be relatively simple to amend the hemp regulations, or simply direct the Ministry of Health to interpret them as allowing cannabinoid extraction. Alternatively, s14 of MoDA 1975 should be amended to allow licences to be issued for making products. This is our preferred outcome as it needs to happen to enable other parts of this Bill, discussed below.

19. There remain some ongoing reporting requirements for prescribers and pharmacists. We are concerned that for many it will remain too hard and too risky for them to prescribe unapproved CBD products. Registering any CBD products as approved medicines will require clinical trials, which could take years, and can only be conducted using GMP certified cannabis. Unapproved CBD products will also need to be GMP-grade.

20. For many patients funding and affordability is a key issue. Pharmaceutical-grade CBD products like *Epidiolex*® are made artificially expensive through onerous requirements and overly expensive shipping, storage, and security protocols. This puts legal products out of reach for many patients, especially compared to growing their own, or making it from local hemp. By taking a herbal remedy or food-based approach, local and affordable CBD products could be available in New Zealand more quickly and cheaply.

S5 & S6: Exemption and statutory defence for terminal patients

21. This clause amends s7 of MoDA to create an exemption and statutory defence for terminally ill patients to use, possess and obtain cannabis, and amends s13 of MoDA to allow terminal patients a defence against criminal charges of possessing a cannabis utensil.

22. NORML supports a compassionate approach which exempts legitimate patients from prosecution. We do not support limiting it to terminal patients, or structuring it in the way currently proposed, for the following reasons.

23. While many terminally ill patients will benefit from the proposed legal defence, it is an incomplete protection. It gives terminal patients no legal way of accessing cannabis. Many terminally ill people will be unable to cultivate their own cannabis without assistance. There may be pressure on their family members and friends to illegally cultivate or illegally procure cannabis for them. The proposed bill encourages criminal activity by friends and family members, while giving those caregivers no legal protection for their compassionate actions. We therefore request that this clause is expanded so that any caregiver designated by the patient can, like the patient, possess a legal certificate which would exempt the caregiver from prosecution. This can be achieved by adding a Clause 5 (2C): “has a certificate stating that the patient has designated this person as their caregiver for the purposes of obtaining cannabis”.

24. We also request that the word ‘cultivates’ is added to Clause 5 (2A) to make it clear that the patient or caregiver can cultivate cannabis. Patients and their caregivers can cultivate their own cannabis in Canada, as well as in the majority of US states where medicinal cannabis is legal. Numerous patients and caregivers in New Zealand tell us that they already cultivate their own cannabis and want to continue to do so. The majority of cannabis patients tell us they do not need pharmaceutical accuracy in dosing. Self-cultivation is the most economically efficient way for these patients to obtain herbal cannabis.

25. Clause 4 defines a terminal illness as “an illness from which a person can be reasonably expected to die within 12 months”. This definition is problematic on both scientific and ethical grounds, and should not

be enshrined in law. Doctors may give general life expectancies but are often wrong. Helen Kelly herself exemplified this; doctors told her at one point that she had two months to live, but she lived nearly two years from that point in time. The arbitrary definition of a 12-month period puts undue pressure on doctors to make an uncertain and unscientific determination of lifespan. This is an unfair burden to put on both doctors and patients. There will be pressure on doctors to make a 12-month certification; and ironically, the doctor may fear professional repercussions if the patient outlives that determination. Putting doctors in the position of expecting or looking forward to their patients dying by a particular date creates an untenable ethical quagmire for doctors.

26. The problem of defining a 12-month timeframe for 'terminal illness' is further compounded by the fact that cannabis has been shown to extend lifespan in cancer patients. Numerous laboratory studies have shown that THC, one of the active compounds in cannabis, has anti-tumour effects, causing apoptosis (death) of cancer cells.[32] One study was recently completed in the UK using 25 mg THC, 25 mg CBD t.i.d. on glioblastoma (brain tumour) patients. Despite this being a relatively low dose of cannabis, the treated groups had a 40% increase in survival time.[33] Given that cannabis can extend lifespan for terminal cancer patients, the arbitrary 12-month definition of terminal illness becomes even more unscientific.

27. In addition to the above reasons, from a moral perspective we see no reason to limit the protections of clauses 5 and 6 to patients with terminal illnesses. We recommend replacing the term 'terminal illness' in these clauses with the phrase 'terminal illness or chronic and debilitating medical condition, where a doctor has recommended the use of cannabis'. Why should someone be allowed herbal cannabis if they're about to die – but not if they're consigned to a life of intractable chronic pain with no end in sight? We understand that the medicinal cannabis scheme referred to in Clause 7 is intended to provide relief for non-terminal patients, eventually. However, the Minister of Health has said publicly that it could be two years before products are available[34]; and the proposed legislation gives no guarantee that such products will be affordable for the majority of patients. Meanwhile, legitimate patients continue to be prosecuted and continue to have their medicine confiscated by police. Any patient with a serious condition who has their doctor's support, as well as that person's designated caregiver, deserves amnesty from prosecution.

28. The protection given in Clause 5 (3A) is not strong enough. Documents released by the Ministry of Health[35] indicate that the Government is aware that there will be police and court time involved in cases of terminal patients who wish to defend a charge. Instead, patients and caregivers should be able to submit their documentation prior to being taken to court. We request that the law specify a mechanism for this, so that prosecution of legitimate medicinal users is avoided altogether, rather than simply allowing the patient to "give evidence" of their illness in court. For any patient, but particularly for a terminally ill person, having to defend a charge in court is likely to be a traumatic experience. It is unfair to put sick people through the court system and is a waste of both court resources and patients' resources.

29. We support the exemption applying to utensils, as these are not only harm reduction equipment that benefits the patient and makes dose titration easier, they also currently have a higher penalty under the

[32] For example: *Guzman M., Cannabinoids: potential anticancer agents. Nat Rev Cancer 2003;* 3*:* 745*–55. Example of research on specific cancers:* Carracedo et al, Cannabinoids Induce Apoptosis of Pancreatic Tumor Cells via Endoplasmic Reticulum Stress–Related Genes, *Cancer Research* July 1 2006 (66) (13) 6748-6755.

[33] "GW Pharmaceuticals Achieves Positive Results in Phase 2 Proof of Concept Study in Glioma", 7 Feb 2017, https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-achieves-positive-results-phase-2-proof-concept-study-glioma

[34] Jones, N. "Medical cannabis legislation introduced to 'ease suffering'." *New Zealand Herald*, 20 Dec 2017.

[35] Ministry of Health, Coversheet: Medicinal cannabis 100-day action, https://www.health.govt.nz/system/files/documents/pages/coversheet_medicinal_cannabis_100_day_action.pdf

Misuse of Drugs Act. Whereas use or possession of cannabis attracts a fine of up to $500 and/or 3 months imprisonment, the penalty for a utensil is up to $1000 fine and/or up to one year imprisonment. This is grossly unfair and unjust. It means police diversion may not be offered as a utensil is considered to be more serious under current law. It results in harsher judgements and less likelihood of an alternative resolution. We recommend the exemption for utensils be applied to equipment used to cultivate or manufacture medicinal cannabis. We note a review of the current regulation of drug utensils was initiated in 2016 but appears to have been abandoned, after all submissions supported changing the current approach.[36]

S7: Regulation-making powers for new standards

30. This clause amends s14 of MoDA 1975, to allow new regulations to prescribe the minimum quality standard that must be met by a product or class of product that contains a controlled drug; and that may be manufactured, imported, or supplied under a licence granted under this Act.

31. In the context of statements made by the Government, this appears aimed at encouraging domestic production, and allowing a standard for cannabis-based products that differs in some way to the usual standard for medicines. NORML supports having new standards that provide for a range of products between food grade and pharma grade. A strict pharma grade will be too difficult for many producers to obtain, and this greatly reduces affordability and options for patients.

32. Although the new regulations are not part of this Bill, they will be derived from it and it's appropriate to give some indication of what form we recommend they take.

    a. NORML supports the intention to encourage domestic production, in order to reduce costs and increase options for patients. We strongly support the stated focus on safety and quality – and suggest there could be more emphasis on affordability.

    b. NORML supports encouraging Craft Cannabis, not just Big Cannabis. We suggest looking to Canada, Israel, and the US states, where a range of producers offer a variety of products at all price points, and we recommend taking care when drafting the new regulations that they do not become a *de facto* prohibition, locking out local producers.

    c. Workers with cannabis convictions should not be prohibited from entering the industry. We recommend police checks should exclude cannabis convictions, and they should not be included in any assessment for licences.

    d. When developing the new regulations, we recommend separating out balms, tinctures, juices or smoothies, which should be treated as herbal remedies.

    e. If we are serious about affordability we should also allow self-provision of natural forms of cannabis, which is common overseas. Two hundred million Americans can access herbal cannabis legally.

S8: Review process

33. This clause inserts a new s35E into MoDA 1975, to create a review and report on the operation of 7(2A) and (3A) to be commenced within two years of the enactment of this Bill and completed within 12 months. The report must include recommendations to the Minister on the implementation of the exception and defence provided by section 7(2A) and (3A) for persons who are terminally ill; and whether any amendments to those provisions are necessary or desirable.

[36] https://www.health.govt.nz/publication/review-drug-utensils-regulation-discussion-document

34. Consistent with our comments above (paragraph 13) we believe any review undertaken of this legislation should be appropriately supported and resourced. It should also be evidence-informed, i.e. not rely solely on scientific facts, but also accommodate the experiences of patients and clients, along with practitioners and other professionals[37].

35. Along with the specific cases noted above, consideration should be given to examining reports of cases (at least quantitatively) where seriously and chronically ill patients, acknowledged as such by their physicians, have suffered legal interdiction as a consequence of their use of cannabis for medicinal purposes, i.e. those not having a terminal diagnosis.

36. Terms and membership for the committee/s:

    a. The review of the legislation should be carried out independently of the MoH.

    b. Patients, whānau and providers should be represented on any advisory committee/s.

    c. Professionals (physicians, nurses, other health professionals, police, judiciary etc.) known to be hostile to the use of cannabis-based medicines should be avoided.

    d. While the focus of the review would remain on medical efficacy, the broader societal impact of the legislation should also be considered. Therefore, appropriately qualified academics and professionals (researchers, lawyers, social workers) should also be involved. Ideally the former would have some prior understanding of the phenomenon (for example, there are a number of internationally acknowledged New Zealand medical and social scientists with established expertise relevant to medicinal cannabis efficacy, use and policy).

37. Thank you for considering this submission and giving us the opportunity to represent the views of patients, caregivers, and advocates. Please advise if we can assist in any way.

[37] Nevo, I., & Slonim-Nevo, V. (2011). The myth of evidence-based practice: Towards evidence-informed practice. *British Journal of Social Work*, *41*(6), 1176-1197.

Appendices

APPENDIX 1: ABOUT NORML

NORML New Zealand was founded in 1980 as a non-profit incorporated society that campaigns for an end to cannabis prohibition. We are an independent, New Zealand-run, organisation. We support allowing adults to use, possess and grow their own cannabis. We recognise that some commercial market for marijuana will always exist, and we therefore promote ways to best to control that market. Approximately half our members say they use cannabis for medicinal purposes.

Our aims are to:

- Reform New Zealand's marijuana laws
- Provide neutral, unbiased information about cannabis and its effects
- Engage in political action appropriate to our aims
- Inform people of their rights
- Give advice and support to victims of prohibition

NORML believes drug policy and associated laws should:

- Have realistic goals;
- Be regularly evaluated, be shown to be effective or be changed;
- Take account of the different patterns and types of harms caused by specific drugs;
- Separate arguments about the consequences of drug use from arguments about morals;
- Be developed in the light of the costs of control as well as the benefits;
- Ensure that the harms caused by the control regimes themselves do not outweigh the harms prevented by them;
- Provide the greatest level of harm reduction for drug users, their families, and their communities;
- Minimise the number of drug users who experience problems from their drug use;
- Be evidence based, as well as having the support of the community.

APPENDIX 2:

Examples of regulatory medicinal cannabis models, with emphasis on patient authorisation and patient access

GMP, Good Manufacturing Practice; CSA, Controlled Substance Act; NSW, New South Wales

	Laws and regulations	Authorised sources	Patient authorisation	Patient access
Herbal cannabis, medicinal grade or other herbal products subjected to some quality control				
Licenced growers and centralised distribution				
The Netherlands[A]	Guidelines for Cultivating Medicinal Cannabis, Annex to the Regulation of the Minister of Health, Welfare and Sports GMT/BMC 2340685	Licensing of a grower by an agency (The Office of Medicinal Cannabis) that takes possession of all cultivated cannabis by a sole grower (Bedrocan) and distributes it Quality adheres to GMP for herbal medicines	Doctor's prescription presented at pharmacy, approved by the Ministry of Health	Herbal cannabis dispensed via compounding pharmacies
The Czech Republic[B]	Narcotic Control Act no. 167/1998; Medicines Act no. 387/2007 (both amended in 2013 with medicinal cannabis provisions)	Licensing of multiple growers by an agency that takes possession of all cultivated cannabis and further distributes it Import of medicinal cannabis from abroad Quality adheres to GMP for herbal medicines	Doctor's prescription; the doctor has to receive approval to prescribe from the State Agency for Medicinal Cannabis	Herbal cannabis dispensed via compounding pharmacies
Australia, federal level	Narcotics Amendment Bill, Act. No. 12/2016; patient access and authorisation to be regulated at the state level (e.g. Access to Medicinal Cannabis Act 2016 in Victoria)	Licensing of multiple growers by an agency that takes possession of all cultivated cannabis and further distributes it Production has not yet started: a distribution model is yet to be established – and may end up conforming to the description of: licensed growers with dispersed distribution (see below)	To be regulated at the state level (e.g. Access to Medicinal Cannabis Act 2016 in Victoria specifies that an authorised prescriber can apply for a patient to become part of the scheme)	To be regulated at the state level (e.g. Draft Public Health Medicinal Cannabis Bill 2016 proposes authorised compounding pharmacies as dispensing sites)
Licenced growers and dispersed distribution (in some U.S. states, cultivation by patients is allowed too)				
Israel	Resolution No. 1587 of the Government of Israel dated 26 June 2016 (little regulation before then)	Cultivated by authorised producers in accordance with the good practices of the Medical Cannabis Unit, Ministry of Health) Details on cultivation by patients and/or caregivers not available	Documented health condition and registration with the Medical Cannabis Unit, Ministry of Health	Dispensed via an auxiliary system of home deliveries and clinics
Canada[C]	Access to Cannabis for Medical Purposes Regulations – ACMPR (SOR/2016–230), Narcotic Control Act, Government of Canada	Cultivated by licenced producers authorised by Health Canada (quality has to correspond to Pest Control Products Act and to the standards for herbal medicines for human consumption under Schedule B of the Food and Drugs Act) Can be cultivated by patients and caregivers (without official quality control mechanisms)	Documented health condition and registration with a licenced producer or with Health Canada (if cultivated by patients or caregivers)	Shipping of up to monthly supply of medicinal cannabis by the licenced producer or provision by a health practitioner (dispensaries not authorised, but in operation) Patients and/or caregivers can be exempted from criminal procedures in relation to cannabis possession and small-scale cultivation up to a certain amount

Table 2. (*continued*)

	Laws and regulations	Authorised sources	Patient authorisation	Patient access
USA: selected states[D]	State-level medicinal cannabis laws (e.g. Delaware Medical Marijuana Act, Senate Bill 17, 2011; or Arizona Medical Marijuana Act 2012; at the same time Schedule I substance in the US Federal CSA)	Cannabis cultivated for dispensaries upon state-level authorisation and quality control regulations (if applicable) In some states can be cultivated by patients and caregivers too (without official quality control)	Documented health conditions and/or doctor's recommendation Patient cards, registries or similar	Medicinal cannabis dispensaries (retail outlets for authorised patients) Can be cultivated by patients and caregivers in some states
Herbal cannabis, no quality control				
Cultivation by patients and/or caregivers or purchased on the illegal market				
USA: selected states (other)[E]	State-level medicinal cannabis laws and regulations (e.g. Alaska Statute Title 17, Chapter 37, 'Medical Uses of Marijuana'; Schedule I substance in the US Federal CSA)	No official source of medicinal cannabis; Can be cultivated by patients and caregivers	Documented health conditions and/or doctor's recommendation to use medicinal cannabis and entry into a medicinal cannabis patient registry	Patients and/or caregivers exempted from criminal procedures in relation to cannabis possession and small-scale cultivation up to a certain amount
NSW, Australia	Medicinal Cannabis Compassionate Use Scheme (police guideline)	No official source of medicinal cannabis Cultivation not allowed	Documented terminal health condition and registration with NSW Department of Justice	Patients and/or caregivers exempted from criminal procedures in relation to cannabis possession, up to a certain amount, but not small-scale cultivation

[A]In the Netherlands, cultivation of up to five cannabis plants is, under certain circumstances, tolerated by the law. This does not apply to medical patients specifically and does not make up part of the official medicinal cannabis policy. Similarly, anyone can buy cannabis in coffee shops (there is no official quality control of cannabis sold there).
[B]In the Czech Republic, cultivation of up to five cannabis plants for personal use is not a criminal offence. This does not apply to medical patients specifically and does not make up part of the official medicinal cannabis policy.
[C]In Canada, the current act governing medicinal cannabis is a merger of the repealed Marihuana Medical Access Regulations SOR/2001–227 (MMAR), which allowed cultivation of cannabis by patients and their caregivers and access through a single, government-contracted producer, and the Marihuana for Medical Purposes Regulations SOR/2013–119, which was meant to replace the MMAR with a model with multiple licenced producers. However, the Canadian courts ruled that it was unconstitutional for the licenced producers to be the only source of medicinal cannabis to patients; hence, the comprehensive ACMPR was adopted. In parallel to these developments, unauthorised dispensaries have been operating in Canada; their legal status remains uncertain.
[D]Cannabis dispensaries are available, but no patient or caregiver cultivation is allowed in Delaware, District of Colombia, Maryland, New Jersey or Washington (for details, see Pacula *et al.*[6] or Americans for Safe Access Legal Information by State & Federal Law[39]). Cultivation by patients is allowed alongside an existing system of dispensaries in Arizona, California, Colorado, Maine, Michigan, Montana, Nevada, New Mexico, Oregon, Rhode Island and Vermont.
[E]Alaska and Hawaii.

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