

19 March 2018

To the Health Select Committee
Parliament Buildings
WELLINGTON

This is a submission on the Misuse of Drugs (Medical Cannabis) Amendment Bill.

The following points are our recommendations:

- a) Cannabidiol (CBD) is not defined as 'an isomer of tetrahydrocannabinol' (THC) under Schedule 2, Part 1, Clause 1 of the Act and should be treated the same as other non-THC cannabinoids and bioactives.

Medical cannabis products should have a percentage restriction placed on the THC content as a proportion of total cannabinoids, as opposed to restricting the levels of other cannabinoids.

THC levels allowed for under different types of medicine control should be determined by independent science and included in regulations by the end of 2018.

- b) The amendment to Section 14 1A should explicitly allow for the making of regulations to prescribe the minimum quality standard for the export of pharmaceutical grade medicinal cannabis.
- c) Tax revenues from licensed producers to be set aside for a cannabis specific funding scheme administered in the spirit of PHARMAC's NPPA scheme.
- d) People with old convictions for cannabis should be able to work in the industry under specific conditions outlined in the new regulations.
- e) Medicines made in New Zealand will be more affordable than imported options and will be even cheaper if they are subsidised directly by tax revenue from the industry.
- f) Allow anyone who has the written endorsement of their doctor to use cannabis as medication along with a nominated caregiver to provide the cannabis without prosecution.

We would like the opportunity to make a supplementary submission once the draft regulations are made public.

We would like to speak to this submission.

BACKGROUND

Hikurangi Group is a group of social enterprises including charitable entities, joint ventures and private companies, with a focus on biotechnology for medicines and natural health products based in Ruatoria. Hikurangi entities have been leading the development of New Zealand's first vertically integrated medical cannabis company with breeding, growing, processing, manufacturing, marketing and distribution capabilities and infrastructure.

We are currently finalising plans for a 10,000m² pharmaceutical grade growing and processing facility on the outskirts of Ruatoria that meets the strictest international security requirements and is cGMP compliant.

Hikurangi is in the process of taking the first New Zealand grown and owned CBD product through a Phase 1 clinical trial in the next 12 months and has a world-class team of independent medical researchers ready to start the work as soon as we provide the product. Our plants have been through what we understand may be the first CO₂ Supercritical Fluid Extraction of cannabis in New Zealand and ESR testing results on those extracts have given us confidence to accelerate our building plans, establish a genetics and breeding programme with Scion Research and prepare for medicine manufacturing to start as soon as the regulations are in place and a licence granted to start commercial production.

We have export orders conditional on this enabling legislation passing that will create at least 120 jobs and revenues of \$160 million in the next three years. We are in discussions with another three customers in Europe and North America for similar deals and have established relationships with partners in other parts of New Zealand who are interested in participating in what could easily be a billion-dollar industry for the country by 2020.

While we appreciate the desire for a precautionary approach by government as regulators on behalf of the public, we cannot emphasise enough the urgency of the agency charged with overseeing the domestic industry establishing itself and industry standards quickly. New Zealand has a lot of catching up to do but is in a great place to learn from the mistakes of other jurisdictions and create a gold standard industry that like many of our other products has the trust and confidence of consumers and is the envy of other countries.

Thousands of New Zealanders suffer from debilitating conditions that clinically-proven cannabis products can assist with – it is not a silver bullet to cure every ailment, but thousands already find real relief from unreliable or expensive forms of cannabis, when as a country we can develop the opportunity to offer clinically proven products at prices everyone can afford.

Further details on recommendations:

a) CBD

1. ESR and many other scientists have provided sufficient evidence to give Parliament confidence that CBD does not need to be treated in law as an isomer of THC. The WHO have agreed that CBD has no psychotropic effects, is not addictive and cannot be overdosed on.
2. Inconsistencies between the way potentiating molecules in cannabis and other natural organisms are regulated should be looked at as part of the current legislation and in associated regulations.
3. While THC and CBD are the focus of this legislation, there are many other cannabinoids and terpenes found in other plants and organisms used in health products and foods. There is little or no regulation around the consumption of these cannabinoids and terpenes despite their effects on human physiology and their ability to potentiate and interact with other medicines.
4. We recognise that CBD, THC and other compounds found in cannabis can potentiate and interact with other medicines. Subsequently, there needs to be warnings about the risks of taking CBD products with other medications and alcohol, and we suggest there are dose limits on all CBD products.
5. We support the recommendation of Medical Cannabis Awareness New Zealand (MCANZ) that CBD products produced according to Good Production Practices (GPP) regulations similar to the [system used in Canada](#) that have a CBD:THC ratio of 20:1 should be Pharmacist Only medicines and anything with a higher ratio of THC should be Prescription Medicines.
6. The Explanatory Note to the Bill says “...no pure cannabidiol product made to reliable quality standards is currently available.” We would draw the Select Committee’s attention to the lack of clinical evidence suggesting a pure cannabidiol product is an effective treatment, nearly all “CBD” studies published to date have been based on products containing other cannabinoids and a growing body of evidence highlights the benefits of the entourage effect when CBD and other bioactives produce synergistic beneficial effects.¹

b) EXPORT

1. We recommend adding a comma and the word 'exported' after the word 'imported' in Section 14(1A) to make it explicit that medical cannabis including flower, cannabis-derived medicines and active

¹ Iffland K, Grotenhermen F. An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies. *Cannabis and Cannabinoid Research*. 2017;2(1):139-154. doi:10.1089/can.2016.0034.

pharmaceutical ingredients may be exported and the Minister can determine the minimum quality standards for those products. Export must be consistent with s.14(5) that ensures medical cannabis exports are only supplied in accordance with INCB guidelines to ensure the destination is a medicines producer or supplier.

2. The Medicinal Cannabis regulatory scheme should ensure New Zealanders have access to affordable medical cannabis products. The best way to do this is to enable New Zealand companies to export to global markets on the condition that they offer products to New Zealanders at affordable rates for people on modest incomes. New Zealand producers who export could be required to offer a proportion of products at cost price, or alternatively at a price set by regulators on a pro-rata (cost per gram of cannabinoid) basis.
3. New Zealand has a unique, unparalleled opportunity to leapfrog other nations (like Australia who are [scrambling to pass new regulations allowing for export](#)) and become a leader in the highest quality medical cannabis products in the world. We have the science and technology expertise; outstanding growing conditions; and most importantly, a global brand for producing safe primary products of the highest quality.
4. If the Bill explicitly enables export of product manufactured here, New Zealand can move quickly to have hundreds of millions of dollars' worth of medical cannabis export orders within 12 months. These would be some of the highest value primary products ever exported from New Zealand, with existing conditional orders (already placed) paying up to US\$5,000 per kilogram for 75% CBD extract. The filling of these orders will provide unprecedented employment opportunities in rurally isolated parts of the country like Northland and Tairāwhiti, in terms of the number of people employed, the wages being offered and the indirect benefits and jobs created in support sectors and host communities.
5. The Bill should explicitly allow for the export of:
 - i. processed medical cannabis products manufactured in accordance with the Code of GMP for Manufacture and Distribution of Therapeutic Goods; and
 - ii. CBD products produced according to GPP regulations similar to the regulations in Canada.
6. The Medicinal Cannabis regulatory scheme should include the application requirements for obtaining an export permit/licence. A clear process will reduce compliance costs and assist producers to comply with New Zealand's international obligations. The Canadian 'Access to Cannabis for Medical Purposes Regulations' includes export permit requirements as will the proposed Australian Medicinal Cannabis export regulations.

c) EMPLOYEES

1. We understand that security is of paramount importance to prevent the risk of product diversion. We are keenly aware of the added security challenges that an industry of this nature faces, and we have taken extensive measures, with support from international experts, to put world-class policies, procedures, and systems in place that will provide comprehensive protection, not only for our physical plant and inventory, but also for our employees and customers. We are confident our security systems will meet or exceed the regulator's requirements.
2. Currently a Medical Cannabis license requires Police clearance checks for all individuals working in or residing at the licensed property. We support the need for this check and full disclosure between licensees, MOH, Police and those working in the industry.
3. In setting appropriate levels of employee screening for New Zealand's Medical Cannabis Regulatory Scheme some guidance can be sought from what is done in comparable jurisdictions.

Canada

The Canadian Medicinal Cannabis Regulatory Scheme requires "security clearance" for the licensee including all officers and directors of a corporation holding a licence, and also for responsible persons "in charge". Factors that are relevant to granting a security clearance include drug convictions and serious criminal offences occurring during the period of 10 years before employment, as well as involvement in a criminal organisation. However, convictions are not in themselves disqualifying but rather are factors that must be taken into account so as to determine 'that the applicant does not pose an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use'

There is no legal requirement that other employees receive a security clearance or undertake screening. However the scheme requires:

- in all areas where cannabis is present a responsible person is present while other persons required by their work responsibilities to be in those areas are there;
- all transactions involving cannabis must be performed with the responsible person physically present;
- and visual monitoring and recording, an intrusion detection system, access to areas where cannabis is present restricted to persons whose presence in those areas is required by their work responsibilities and record keeping of all people entering restricted areas.

Australia

Australia also has strict screening requirements for licensees. However the regulations allow consideration where the applicant may have been involved in prior "compassionate" cultivation or supply of cannabis for

medicinal purposes. The guidelines state that “the existence of such exemptions does not guarantee that in such cases a licence would be successful”.

The regulations also require the hiring of “suitable staff”. A person is considered unsuitable if he or she:

- has been convicted of a serious offence, any drug offence or an offence involving theft during the period of 5 years before employment,
 - has a history of drug use.
4. New Zealand’s Medical Cannabis Scheme does not necessarily need to exclude people with historic cannabis convictions from working in the industry. Many of these people want to work in a legitimate industry and use their skills to earn money for their family without the threat of prosecution or fearing for their safety. Their convictions are often a barrier to other forms of legitimate employment but with sufficient security systems and supervision (both in person and camera surveillance), there could still be a place for them in this industry.
 5. We recommend that the New Zealand Regulatory Scheme bases its security screening around what is necessary to protect public health, safety and security, including preventing cannabis from being diverted to an illicit uses. We do not think this means excluding all people with cannabis convictions. Provided the license holder demonstrates they have sufficient security systems, HR policies and production processes to mitigate any risk of offending relating to cannabis.

We recommend two levels of screening regarding conviction history, as is done in other jurisdictions. We prefer past offending to be considered as relevant factors that must be considered by the governing agency (as is done in Canada) rather than as automatically disqualifying the applicant from employment in the industry.

Levels of screening:

- ii. Responsible persons (licensees, supervisors) and persons required to handle highly refined cannabis extracts. Relevant factors:
 1. Serious criminal convictions during the period of 10 years before employment.
 2. Dishonesty convictions during the period of 10 years before employment (Not including those concealed by the Criminal Records (Clean Slate) Act 2004
 3. Drug related convictions during the period of 10 years before employment (not including those concealed by the Criminal Records (Clean Slate) Act 2004
- iii. Other Staff (in supervised positions). Relevant factors:

1. Serious criminal convictions during the period of five years before employment.
2. Dishonesty convictions during the period of three years before employment. (Not including those concealed by the Criminal Records (Clean Slate) Act 2004)
3. Drug related convictions during the period of three years before employment.

d) COST OF MEDICINES & NUMBER OF LICENCES

1. Hikurangi is committed to delivering affordable access to proven plant-based products for New Zealand patients. On the basis that we will cover most of our establishment and ongoing costs through revenue from exports, we are confident we will be able to provide pharmaceutical grade products to New Zealanders at, or close to, cost price.
2. We agree with MCANZ that new tax revenue generated from the licensed producers could be ring-fenced, for its own funding scheme overseen by PHARMAC with a criteria that only provides subsidy if a specialist attests to the likely efficacy for the particular condition. This would enable funding for those with severe conditions to have a much better chance of affording legal treatments.
3. Parliament may wish to limit the number of Medical Cannabis licenses as has been done in other jurisdictions. Alternatively, it may allow the market to determine what is sustainable. We do not have a strong view on this matter but do note that in jurisdictions that have limited numbers of licences there seems to be the ability for regulators to ensure the highest standards are maintained by licenced producers and suppliers.

e) SCOPE OF EXCLUSIONS

1. Patients require access to a range of product options and we recognise the need for patients to access the relieving and healing properties of the plant in a range of ways.
2. We support the MCANZ recommended inclusion of "severe or debilitating condition" that covers conditions more broadly than terminal conditions, whilst also only including those at the severe end of the spectrum that the public has greatest sympathy for.
3. Any medicinal cannabis user who has their doctor's professional endorsement, regardless of the specific medical condition, should be free from prosecution under the Act.