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URGENT

The Associate Minister of Health
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WELLINGTON

cc The Minister of Customs
The Director-General of Health
c/o Stewart Jessamine
CEO Ministry of Customs
The Solicitor-General

Dear Minister of Health, Minister of Customs, Stewart and Una

**NOTICE OF INTENDED LEGAL CHALLENGE RE STATUS OF CANNABIDIOL “CBD”
UNDER THE MISUSE OF DRUGS ACT**

I write on behalf of various interests who seek urgent clarification of the legal status of Cannabidiol “CBD” under the Misuse of Drugs Act.

In summary:

1. CBD is not explicitly scheduled under the Misuse of Drugs Act.
2. CBD does not meet the statutory criteria under Section 3A for scheduling under the Misuse of Drugs Act¹ as there is no evidence that it poses a very high, high or moderate risk of harm to individuals or to society.
3. Information obtained under the Official Information Act and from the Ministry of Health website identify a significant disagreement within the New Zealand government officials over the status of CBD under the Misuse of Drugs Act. Some from the Ministry of Health claim CBD is indirectly covered by Schedule 2 (1)(2)² as a Class B drug based on their assessment that it is “an isomer of tetra-hydrocannabinols” (THC). In contrast, the government’s

¹ Misuse of Drugs Act 1975 **3A Classification of drugs**

The classification of a drug under this Act is based on the risk of harm the drug poses to individuals, or to society, by its misuse; and accordingly—

- (a) drugs that pose a very high risk of harm are classified as Class A drugs; and
- (b) drugs that pose a high risk of harm are classified as Class B drugs; and
- (c) drugs that pose a moderate risk of harm are classified as Class C drugs.

² The isomers of the substances mentioned in [clause 1](#) whenever the existence of such isomers is possible within the specific chemical designation.

leading expert analytical chemist, Dr Keith Bedford and his expert team at Crown Research Institute Environmental Science and Research, “ESR”, have published a paper explaining why THC is not within this definition, because CBD has a different chemical formula, structure and function to THC and accordingly it is not caught within the definition of “an isomer within the same chemical designation”.

4. Dr Bedford’s expert view has been made clear to the Ministry of Health and to his colleagues on the government’s Expert Advisory Drug Committee (“the EADC”). The minutes of the EADC’s April 2016 identify no scientific or legal reason why Dr Bedford’s view is wrong. It appears the different views relate solely to policy consideration and perhaps vested interests, although it remains unclear to me why some members of the committee would prefer to continue to treat CBD as if it is illegal. Clearly government policy cannot override the law that was written by Parliament, and in particular s3A of the Misuse of Drugs Act.
5. Hemp products can already be sold legally for many purposes in New Zealand, including as hemp seed oil for human consumption and a range for hemp products that can be sold and used as animal food, despite inevitable CBD content. The proposal to legalise all hemp seed foods does not include any proposal to restrict CBD content.
6. A research summary published on the Food Safety Australia New Zealand “FSANZ” website in support of the legalisation of all hemp seed foods (which contain CBD) claims to have reviewed over 1600 papers. It concludes there are no known harmful effects from natural hemp-derived CBD. It includes quotes such as: “In humans, CBD has been tested in rheumatoid arthritis, multiple sclerosis, anxiety and psychosis and shows an EXTREMELY SAFE profile³.” FSANZ is proposing to legalise hemp seed foods despite their inevitable CBD content.
7. Internationally hemp and CBD have been very highly regarded for their nutritional benefits for many thousands of years. Well recognised benefits promoting wellness and assisting to manage a diverse range of health conditions including epilepsy and other seizures, nervous system disorders, pain, nausea, and other chronic conditions involving endocannabinoid deficiencies. CBD and its use has been approved by many states including Canada, over half of the states in the USA and recent law changes in Australia has facilitated its use there. No harmful effects have been identified
8. The US government and courts have recognised the many benefits of CBD. Since 1988 (around the time the US government applied for a patent for medical uses for CBD) senior US government officials such as US

³ Professor Silveira - University of Sao Paulo, Brazil

Administrative Law Judge Francis L. Young for the US Government's Drug Enforcement Agency (DEA) "Findings of fact and conclusions of Law" in "The Matter Of Cannabis Rescheduling Petition, Docket No. 86-22, September 6, 1988:

"It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between people suffering illness and the health benefits offered by Cannabis"

9. Other sections in the Misuse of Drugs Act and related legislation make clear that the intended restriction for THC and extracts of the *Cannabis sativa* plant apply only to THC. In particular:
 - a) Prosecutions under the Misuse of Drugs Act s29B puts the onus on the prosecution to prove that the preparation contains tetrahydrocannabinols (if THC content is raised by the defence);⁴
 - b) The Misuse of Drugs (Industrial Hemp) Regulations permit the hemp plant to be grown under licence and hemp products to be sold, providing the THC content tests within the maximum permitted levels. There is no reference in the Industrial Hemp Regulations to any maximum CBD content, presumably because CBD content was of no concern to the law-makers as it is not psychoactive and has no known harmful effects (and many benefits). If CBD were to be treated as if it were THC for the purposes of the Misuse of Drugs Act and Industrial Hemp Regulations then all the hemp plants in New Zealand would become unlawful, making the Industrial Hemp Regulation redundant, which is clearly contrary to Parliament's intention.
 - c) Hemp oil can be lawfully sold as food in New Zealand. The analyst has set a limit for "THC" in hemp oil, but no limit for "CBD". In OIA response H201602100 a June 2016 Official Information Act, the Ministry of Health identified the level of THC in the product as the only criterion used to determine its legality.
 - d) There is currently no testing facility for CBD in New Zealand, confirming the government analyst has never been concerned about CBD content. ESR has advised it would take approximately one month to set up testing for CBD.

⁴ **29B Special provisions where offence relating to cannabis preparations alleged**

For the purposes of any proceedings for an offence against any of the provisions of [section 6](#) or [section 7](#) in relation to any cannabis preparation the following provisions shall apply:

- (a) it shall be for the prosecution to prove that the preparation to which the charge relates contains any tetrahydrocannabinols:
- (b) subject to paragraph (a), the preparation shall be deemed to have been produced by subjecting cannabis plant material to some kind of processing unless it is in a form that is clearly recognisable as plant material:
- (c) **plant material** means the whole or any part of the leaf, flower, or stalk of any plant (of whatever species):
- (d) the question of whether or not any preparation is in a form that is clearly recognisable as plant material shall, in the event of dispute between the prosecutor and the defendant, be determined by the jury (or, if there is no jury, by the Judge as a question of fact) by means of a visual inspection unaided by any microscope or magnifying glass (other than spectacles ordinarily worn) or by any other device.

Referral to the EACD

10. I have been following the Ministry of Health's referral of CBD to the NZ Government's Expert Advisory Committee on Drugs in April 2016 and have recently obtained the April 2016 minutes and relevant reports. I understand that the Panel deferred its decision to its October 2016 meeting and has still not released its minutes of that meeting, apparently due to disagreement between different factions of that Committee. These documents make clear that the Ministry of Health's current treatment of CBD as if it were an isomer of THC is unlawful, as the expert advice to the Ministry is that as a matter of fact, CBD does not fit that definition, as CBD does not have the same specific chemical designation as Tetrahydrocannabinols. The Ministry of Health cannot rely on procrastination or policy to override the facts or the law.

Unlawful application of Regulation 22(1) of the Misuse of Drugs Regulations

11. It is concerning that the classification of CBD seems to have become a political issue. As a result of the Ministry of Health's approach that CBD is covered by the Misuse of Drugs Act, access to foods, dietary supplements and medicines containing CBD are currently severely restricted in New Zealand.

12. Medicines containing CBD are (in my view unlawfully) treated as if Ministerial approval is required under Regulation 22 of the Misuse of Drugs Regulations, resulting in considerable bureaucratic hoops and hurdles, delay in access and unnecessary cost for patients who are typically already very ill, and their families who are typically already very stressed. The Ministry's requirement for this approval is ultra vires once it is accepted that CBD is outside the scope of the Misuse of Drugs Act.

Medsafe policies

13. The complex situation is compounded by the apparent policy of Medsafe (disclosed in documents obtained under the Official Information Act) to attempt to prohibit foods or other products which contain CBD from being sold as foods or dietary supplements, apparently because CBD is also scheduled under the Medicines Regulations. I can find no lawful basis for this policy and do not understand how Medsafe can reconcile this with the law or with the FSANZ proposal to approve the sale of hemp seed foods for human use. I invite your urgent explanation on this.

Unlawful seizure of CBD by NZ Customs

14. I understand from other Official Information Act responses and from recent coverage on TV3's Story (on the use of CBD as a supplement for managing Alzheimers by Mr Robinson, father of Nicky Evans) and other documentation that I have been shown, that NZ Customs have been instructed to seize products that contain CBD at the NZ border. This is despite the expert advice to the Ministry of Health that CBD has no known harmful effects to individuals or society and it is outside the scope of the Misuse of Drugs Act

schedules. The correspondence I have seen from the Ministry of Health and NZ Customs has inconsistent and evolving explanations and does not disclose a lawful reason why products containing CBD are seized. Due to redactions, it is unclear who at the Ministry of Health is continuing to push the view, their qualifications, why they are doing this or why the Minister and NZ Customs are following that advice in preference to the expert advice of Dr Bedford at ESR.

- 15.** The current policy of Ministry of Health, and adopted by NZ Customs to treat CBD as if it is covered by the Misuse of Drugs Act to try to justify the seizure of products which contain CBD, is in my view unlawful, unreasonable and unjustified as CBD is not covered by the Misuse of Drugs Act. It is contrary to expert advice and is restricting access to nutritious food, dietary supplements and medicines for sick New Zealanders. It creates a complex, slow and unpredictable layer of bureaucracy that discourages sick people, the parents and caregivers of sick children and the elderly and their doctors from using CBD products despite the very considerable health benefits (and consistent absence of harm) that have been reported from natural hemp-derived CBD products in overseas studies. The Ministry's persistence with this policy contrary to expert advice is irrational and indicates bad faith towards the public of New Zealand.

Economic effects from the Ministry's policy

- 16.** The government's ad hoc approach is also discouraging investment in growing and processing hemp in New Zealand, as it is uneconomic for farmers to invest in growing hemp unless they are able to utilise all of its products. Processors, distributors and exporters are also discouraged by the blatant inconsistencies in the government's interpretation of the law and the resulting unpredictability and red tape of investing in this product. The Primary Production committee was briefed on this earlier this year by Richard Barge of the the NZ Hemp industry Association. Officials with various Ministry of Health and MPI officials in attendance.
- 17.** Information obtained from an OIA request in July 2016 to the now Prime Minister Bill English disclosed advice held on his behalf by Treasury. This estimated the public cost to New Zealand of the current drug enforcement policies with police and court time and lost tax revenue of over \$400million per year. This was without allowing for considerable likely savings on imported Pharmac Drugs if New Zealand were to follow the same prescribing patterns as the US where research has shown that prescribing or recommending cannabis has significantly reduced prescription for an array of other pharmaceutical drugs. The Treasury information (consistent with other criticism of the Drug Harm Index) noted New Zealand's Drug Classification System is "not aligned with the relative harms caused by drugs" and the Government's research indicates that legalising the sale of "lower harm" Cannabis extracts "would not have any significant negative impacts".

Suggested way forwards

- 18.** Many New Zealanders are keen to urgently access hemp oil, and other products that contain CBD for a variety of good reasons.

- 19.** Unless this matter can be promptly addressed and satisfactorily resolved, I have instructions to prepare declaratory judgment proceedings to seek rulings from the High Court on the lawful interpretation of the Misuse of Drugs Act in relation to CBD. An urgent application may be required if NZ customs seize CBD product in the meantime.

- 20.** The proposed declarations sought from the Court are:
 - A) CBD is not explicitly prohibited under the Misuse of Drugs Act
 - B) CBD has a different chemical formula and different structure and function to THC and accordingly it is not restricted as “an isomer within the same chemical designation as tetrahydrocannabinols” and is not covered by Schedule 2 of the Misuse of Drugs Act ;
 - C) CBD does not meet the criteria of section 3A for classification under the Misuse of Drugs Act, as it does not cause a very high, high or moderate risk of individual or social harm;
 - D) Products containing CBD do not require Ministerial approval to be prescribed or recommended under Regulation 22(1) of the Misuse of Drugs Act because CBD is not subject to that Act. Regulation 22(1) of the Misuse of Drugs Act does not apply or is being unlawfully applied to medicines and other products containing CBD
 - E) The actions of NZ Customs in seizing or restricting access into or out of New Zealand of products because they contain or may contain CBD is unlawful.

The interests I represent are very keen to progress this urgently. In order to expedite the process and minimise the court time required, I would be very grateful for your urgent feedback on the matters raised in this letter and if we cannot agree that CBD is outside the scope of the Misuse of Drugs Act, then on the wording of the proposed orders. I would be happy to travel to Wellington on short notice to meet with you if this would assist.

Please take notice that if NZ Customs seize any further CBD product from clients I represent in the meantime then an urgent application to Court will be necessary.

Thank you for your urgent attention to this matter that affects the rights and wellbeing of many New Zealanders.

Yours faithfully

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