

We, Hemp4health, along with more than 2500 Australians whose signature can be found within the attached petition, wish to express our objection to the latest proposed amendment to Cannabidiol (CBD) listed within the Consultation: Proposed amendments to the Poisons standard being referred to the June 2018 Meetings.

This proposed amendment is opposite to what the world health organisation's stance and recent assessment of Cannabidiol and its safety, which, as you will read from their website (Link below), their stance on CBD is as follows

"It has been widely reported that WHO officially recommended on December 14, 2017 that cannabis compound cannabidiol (CBD) not be internationally scheduled as a controlled substance."

<http://www.who.int/features/qa/cannabidiol/en/>

We strongly object to this latest proposed amendment to the poison standard, as do the 3000 or more customers and fellow Australians, who have signed our petition to have CBD Removed from scheduling. (See attachment 'Hemp4health CBD Petition Signatures' for Petition Signatures and comments to date. Link also listed below)

<https://www.ipetitions.com/petition/make-cbd-cannabidiol-industrial-hemp-extract-a>

The Proposed changes are related to Cannabidiol (CBD) Schedule 4 (see attached Screenshot from Proposed amendment - link to full Document <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-being-referred-june-2018-meetings-accs-acms-and-joint-accsacms>)

Cannabidiol and tetrahydrocannabinols (THC)	Substance	Cannabidiol	THC
	CAS number	13956-29-1	1972-08-03
	Alternative names	2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (IUPAC).	Dronabinol (INN); (6aR,10aR)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo(b,d)pyran-1-ol (USPDDN); (-)-(6aR,10aR)-6,6,9-Trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol (IUPAC).
	Applicant	Private applicant.	
	Current scheduling	Cannabidiol is in Schedules 4 and 8 of the Poisons Standard. THC is in Schedules 8 and 9 and Appendices D and K of the Poisons Standard.	
	Proposed scheduling	A request has been made to amend the wording of the Schedule 4 entry for cannabidiol to reflect absolute weight per volume of no more than 1% w/v of the product rather than relative to the cannabidiol content. Schedule 4 - Amend Entry CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of where other cannabinoids found in cannabis comprise no more than 1% w/v of the product.	
	Key uses / expected use	Medicines.	
	Reasons for proposal	According to Therapeutic Goods Order No. 93 (TGO 93) ¹⁷ , Standard for Medicinal Cannabis) 4 (2): "...are taken to be active ingredients for the purposes of this order (whether or not those ingredients are specified, disclosed, purported or notified to the Secretary to be active ingredients): a. any tetrahydrocannabinol present in a medicinal cannabis product, the quantity or proportion of which (together with any corresponding acid) is greater than or equal to 1.0% w/w or w/v of the product"	

The proposal seeks to reduce the limit from its current 2% down to 1% of CBD or - 1gram of CBD per 100ml.

This is absurd, especially considering that Australia New Zealand Food Standards recognises that Cannabidiol (CBD) only has a therapeutic effect if taking more than 120mg per day. (See screenshot from ANZFS Document) The government cannot have their cake and eat it as well, when the food standards recognises the therapeutic affect occurs in amounts greater than 120mg per day, and then to all of a sudden, try and restrict the same Substance they have already assessed just because it suits them.



Supporting document 2

Cannabidiol hazard profile – Proposal P1042

Low THC Hemp Seeds as Food

Executive summary

Cannabidiol (CBD), which is structurally related to delta 9-tetrahydrocannabinol (THC), is typically present in low THC hemp seed foods at levels in the low mg/kg range. The pharmacological properties of CBD, and its safety profile, have been the subject of extensive research, including studies in humans. In contrast to THC, CBD binds weakly to cannabinoid receptors and does not cause psychoactive effects. Studies in laboratory animals indicate that the oral toxicity of CBD is low.

CBD administered by the oral route has been investigated in clinical trials in healthy subjects and in patients with various medical conditions. CBD has been shown to be well tolerated at doses greater than 1000 mg per day. No reports of adverse effects attributable to oral CBD were located in the published literature. Regarding efficacy in these studies, the lowest oral dose in humans for which potential therapeutic effects have been reported is 120 mg/day.

As per the Consultation, The reason that has been given for this proposed change you will note is as follows:

"According to Therapeutic Goods Order No. 93 (TGO 93)

(link is external), Standard for Medicinal Cannabis) 4 (2):

"...are taken to be active ingredients for the purposes of this order (whether or not those ingredients are specified, disclosed, purported or notified to the Secretary to be active ingredients):

- a. ***any tetrahydrocannabinol present in a medicinal cannabis product, the quantity or proportion of which (together with any corresponding acid) is greater than or equal to 1.0% w/w or w/v of the product"***

The above listed as **a)** is referring to THC and its acids being THC-A – **tetrahydrocannabinol and its acids!** NOT CANNABIDIOL (CBD) .

This attempt to further restrict CBD, is not acceptable, and is in fact based purely on misdirect and reliance on public confusion of the facts and is attempting to bundle THC (psychoactive component) and CBD (non-psychoactive and deemed safe) into the same basket to restrict Australians Access and Use of this natural substance, for the sole benefit of big Pharmaceutical companies and those within the government who directly or indirectly, benefit from the success of these Pharmaceutical companies.

This attempt further reiterates and confirms that tetrahydrocannabinol (THC and THC-A) and Cannabidiol (CBD and CBD-A) need to be completely separated from one and other by recognising that the differences far out weigh the similarities of each, noting their only real similarity is that they are both found in the Cannabis plant. Once this is has been acknowledged and accepted, that THC and CBD are completely different substances they can then be appropriately regulated, separate from one and other.

This latest proposed amendment is simply a ploy to keep small businesses out of business and well away from this safe, natural and evolving industry that is CBD Hemp! Businesses like ours, Hemp4health, which from late 2015 until early 2017, helped more than 3000's Australians access full spectrum CBD products of the highest quality and safety standards, safe natural products which helped these thousands of people to regain their quality of life, or experience this sensation for the first time. Men, Woman and Children alike, many of whom have suffered for years, have been prescribed and tried endless amounts of prescription medications to no avail and ready to give up on life! The feedback from these thousands of people is testament to the safe and beneficial nature of CBD from Hemp and their first hand experience using such products should be all that is needed to confirm that CBD is SAFE to use as a dietary supplement in line with the views and advice the World Health Organisations has given in relation to Cannabidiol!

This is an industry that is evolving and maturing in the United States and many other countries around the world and there is ABSOLUTELY NO REASON WHY WE CANNOT FOLLOW SUIT HERE IN AUSTRALIA!

A full scale block on this consultation will be launched ASAP via all media outlets in Australia rallying the Australian public's support to block the TGA's consultation from going any further.

This is simply put, a waste of tax payers money and an attempt by greedy pharmaceutical companies who feel threatened by this natural CBD substance which is not a drug! And to try have it removed from the public as it threatens their pharmaceutical drug sales revenue.

The responsibility of the Australian Government is to act in the best interest of the Australian People, and this proposed Amendment to Cannabidiol, is certainly NOT in the best interest of Australians, and scheduling CBD in any capacity, is in contradiction to the recommendations and advices given by the World Health Organisation and organisations a like, whose sole purpose is to research and advise on all health related

topics to encourage a common and worldwide stance of same, to allow uniformity within each Countries regulations.

Proposed Solution

There are many substances that are listed within Australia's Poisons Standard, in a number of schedules, dependant on its purpose and concentration.

For example - Eucalyptus Oil, tea tree oil, Bay Leaf Oil, Orange Oil and Lemon Oil. Page 37 Poisons standard lists the different Substances and the amount/volume of which defines its schedule

For example

Bay Oil (Bay Leaf) is listed in schedule 6 if the volume is 200 millilitres or less.

Basil Oil is listed in schedule 5 if the volume is 200 millilitres or less.

Eucalyptus Oil - Listed schedule 6 if volume is 2 Litres or less

The substances in these schedules must ensure appropriate labelling and containers in order to meet the schedule 5 or 6's requirements, which then allows the substance to accessed and purchased from local stores and supermarkets.

See Below

Anise oil when included in Schedule 5.	200 millilitres or less
Basil oil when included in Schedule 5.	200 millilitres or less
Bay oil when included in Schedule 6.	200 millilitres or less
Cajuput oil when included in Schedule 6.	200 millilitres or less
Cassia oil when included in Schedule 5.	200 millilitres or less
Cineole when included in Schedule 6.	2 litres or less
Cinnamon bark oil when included in Schedule 5.	200 millilitres or less
Cinnamon leaf oil when included in Schedule 6.	200 millilitres or less
Clove oil when included in Schedule 6.	200 millilitres or less

Eucalyptus oil when included in Schedule 6.	2 litres or less
Eugenol when included in Schedule 6.	200 millilitres or less
Fennel oil when included in Schedule 5.	200 millilitres or less
Hydrocarbons, liquid, when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid.	5 litres or less
Hydrochloric acid when included in Schedule 6.	5 litres or less
Leptospermum scoparium oil (manuka oil) when included in Schedule 6	200 millilitres or less
Marjoram oil when included in Schedule 5.	200 millilitres or less
Melaleuca oil (tea-tree oil) when included in Schedule 6.	200 millilitres or less

According to <https://www.medicalcannabisclinic.com.au/cannabis-plant/terpenes-compounds-of-cannabis/>

"Terpenes" are responsible for some benefits we often fail to notice within consumable products. These benefits include the aromas or flavours in beer, sweets, perfume, fruit, incense and much more. Terpenes also offer a diverse array of medicinal and nutritional aspects.

Any given terpene can be found to exist in an incredible variety of different plants. For instance, β -Caryophyllene is found in black pepper, cloves, some cannabis Sativa strains, rosemary and hops

Terpenes provide the single largest array of varied tastes and odours available to a single class of chemical compounds. Terpenes make up the majority of components in flavouring agents found in food, candy and perfume.

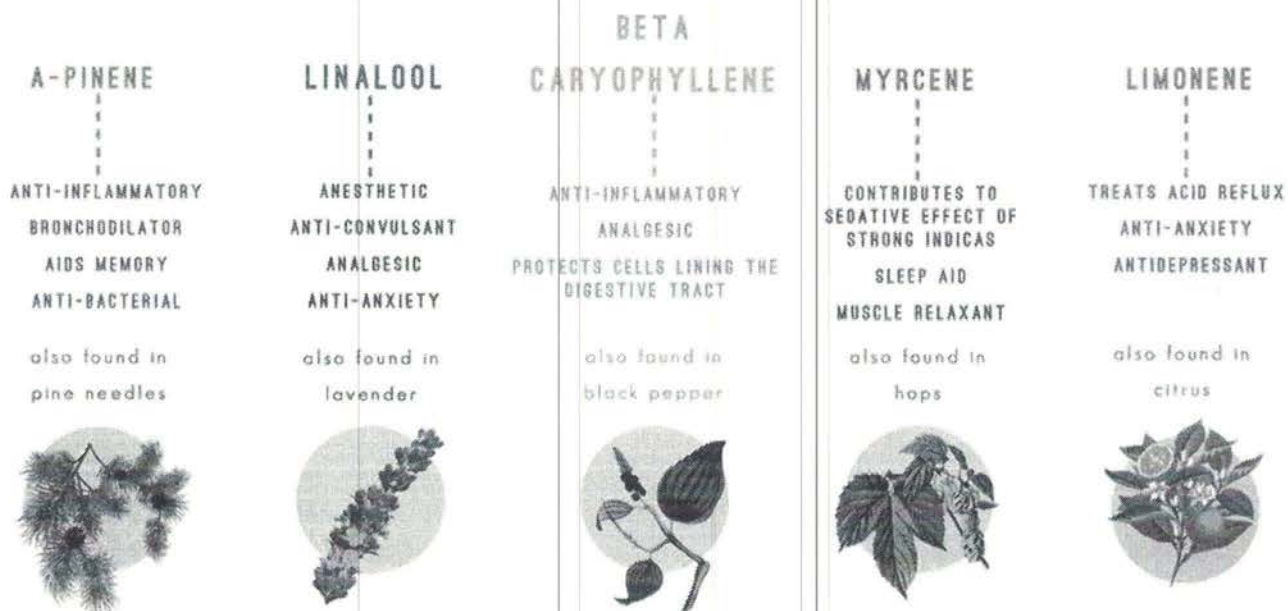
Myrcene is the most commonly found terpene in cannabis.

Myrcene is also found often in the highest concentrations. Myrcene is found in large amounts in hops, aged mango, bay leaves, and lemongrass. The odour varies but is described to have an herbal, balsamic, rooty, and spicy aroma. Its medicinal properties are well known, particularly used to treat pain and inflammation. Myrcene is known to have a calming effect both mentally and physically, which is why it has been used to

treat psychosis and muscle spasms. The properties it encompasses has synergistic effects with other terpenes, like THC for pain, THC-A for inflammation, CBD and Linalool as an antipsychotic.

The second most abundant terpene in cannabis are the Limonenes
Limonenes are terpenes found in the peel of citrus fruit, as well as in other fruits and flowers. Wearing a sweet, fresh fruity odour: the citrus aroma is unmistakable.
Limonenes carry benefits including antidepressant, anxiety-relief, immuno-stimulant (similar to garlic), antitumour, and bacterial / anti-fungal properties. Limonenes aid in treating gastric reflux and treat oesophageal ulcers.
Limonenes can be used topically as an antiseptic agent and are quite effective to repel insects: the leaves of the lemon or grapefruit tree are used for this purpose. Limonenes have synergies with THC-A, CBD-A, CBC-A, CBC, CBG, Caryophyllene-Oxide, and Linalool."

The Below Image is from this same website <https://www.medicalcannabisclinic.com.au/cannabis-plant/terpenes-compounds-of-cannabis/>



You will note that terpenes are present in many different varieties of plant, and are naturally beneficial when consumed or applied and can be found in thousands of different foods and oils around the world.

To draw a comparison to Cannabidiol (CBD), and as an example, you will note that Citrus fruit contain the terpene Limonene, and therefore Substances such as Orange Oil or Lemon Oil, can have beneficial properties and many different uses as a result.

You will note that Orange (bitter) Oil falls into schedule 5 in the poisons standard subject to concentration and use and therefore must adhere to the labelling and container restrictions relevant.

Schedule 5.	Caution – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
Schedule 6.	Poison – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong

You will also note that as of August 2000, Orange (sweet) Oil was removed from scheduling altogether for the following reason:

- 1. Low Toxicity
- and applied to
- 2. Any Use of Orange oil (see below screenshots from poisons standard)

APPENDIX B – SUBSTANCES CONSIDERED NOT TO REQUIRE CONTROL BY SCHEDULING

PART 1 – REASONS FOR ENTRY

a	Low Toxicity.		
b	Use pattern restricts hazard.		
c	Presentation/packaging restricts hazard.		
d	Industrial use only.		

7.	General		
7.1	Any use		

ORANGE OIL, SWEET	Aug 2000	a	7.1
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The above, as well as the numerous other examples that can be found within the poisons standard, proves that there is relevant precedence and evidence confirming that a substance can be listed in a number of schedules, OR, removed completely from scheduling if it meets certain criteria, which, Cannabidiol should meet, due to its low toxicity, safe and natural properties, and the absolute minimal risk and inability for CBD to cause harm if abused.

We believe that there are 2 ways in which CBD (Cannabidiol) can be approached with regards to its placement within a schedule:

1. Remove CBD altogether based on the above low toxicity and the confirmation of its safety via the advices and research made by reputable organisations such as World Health Organisation.
2. List CBD Cannabidiol in schedule 5, except:
 1. a) in preparations **OTHER THAN as a dietary supplement with a maximum daily CBD intake amount of no more than 120mg per day OR the equivalent of 2mg per kg of body weight per day** (warning label affixed advising daily limit of 120mg per day and packaged in appropriate containers relevant to schedule 5) ;
 2. b) in medicines for human therapeutic use, **and classified as such based on a daily intake amount of MORE THAN 120mg per day**, that are to be used when compliant with the requirements of the Required Advisory Statements for Medicine Labels;

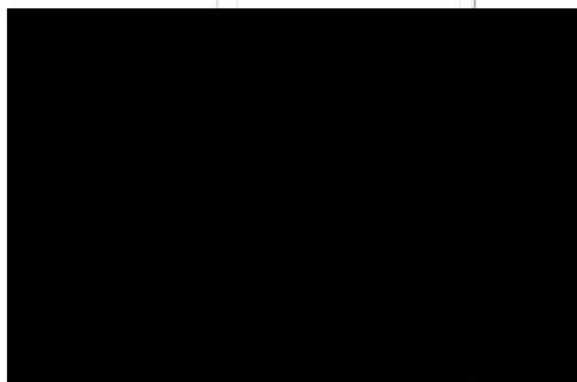
Any product that is intended to be taken at amounts more than 120mg per day of Cannabidiol can be left in schedule 4 as a therapeutic product. The Australia New Zealand Food Standards already advised and acknowledges that Cannabidiol has no therapeutic benefit if less than 120mg per day is consumed.

There is absolutely no reason why one of the above suggestions cannot be implemented as a matter of urgency! This is a logical solution that benefits all Australians, and one that would see Australia up and in line with much of the world and prove that we are a progressive Nation, who is open and receptive of the CBD Hemp industry and the many benefits and opportunities it brings with it. Benefits like boosting our economy, enhancing our agricultural industry and showing the world that Australia is indeed the land of opportunity and a fair and just country that allows its people to live as adults and take advantage of what Nature has offered people around the world for thousands of years!

We trust that the above will be seriously considered and implemented in due course.

Regards

Hemp4health



Rod Kight is an award winning lawyer, advocate, and author focusing his efforts on supporting providers, farmers, manufacturers, scientist, laboratories, and the retail industry surrounding the commerce of industrial hemp and legal recreational and medical cannabis. He is based in North Carolina in the United States, however, has some compelling and accurate advice and information with regards to Cannabidiol (CBD), how it is regulated in the United States and why the US is not in violating any of the United Nations treaties to which, like Australia, they are signatory to.

The following Extracts are taken from Rod Kights website, which, clearly summarises how CBD and industrial Hemp is regulated and defined in the United States. The SAME separation and definition of Industrial Hemp and CBD needs to be **immediately** replicated and implemented in Australia and the following confirms that there is absolutely **NO REASON** whatsoever, for Australia not to adopt the same stance successfully.

<https://cannabusiness.law/articles/>

"The legal status of CBD is an issue that continues to confuse people, including law enforcement. It's actually a simple matter, though misinformation (and disinformation) have caused significant uncertainty.

*In the wake of a big week for CBD I thought it would help to discuss the Source Rule, which I developed (initially as the "Source Theory") and articulated for the first time in a **blog post on September 30, 2016**. Applied properly, the Source Rule quickly and directly determines whether CBD is lawful under a given set of circumstances. It can be summarized in a sentence: CBD is legal- or not- based on its source.*

*There are at least three, and arguably four, legal sources of CBD: (1) CBD derived from industrial hemp lawfully grown in the US (**2014 Farm Act**); (2) CBD derived from non-psychoactive hemp lawfully grown outside the US (**2004 HIA v. DEA case**); and (3) CBD derived from the mature stalks of the marijuana plant (**Controlled Substances Act**). Also, (4) if CBD is derived from anything else that is not a scheduled drug then it is lawful. (As with any legal concept, there are collateral and sub issues with respect to each of these sources; however, they are beyond the scope of this article. I've written about them in depth in a **September 2017 article for the Cannabis Law Journal**.)*

Source reference:

<https://cannabusiness.law/cbd-and-the-source-rule/>

Also refer to:

The Cannabis Law journal

<https://journal.cannabislaw.report/usa-the-legal-status-of-cannabidiol-other-cannabinoids-terpenes-derived-from-industrial-hemp/>
and

<https://cannabusiness.law/an-open-letter-to-industrial-hemp-and-cbd-businesses/>

The extremely Important distinction and separation of Hemp & Marijuana!

From Rod Kights Article titled **Industrial Hemp & CBD**

<https://cannabusiness.law/services/hemp-cbd/>

*"The terms "hemp" and "marijuana" are mostly misleading. Both are the plant *cannabis sativa* and, in fact, are biologically indistinct from each other. The sole difference between them is their respective concentrations of tetrahydrocannabinol, commonly known as THC. This is the cannabinoid that "gets you high." It also has a wealth of medical benefits. Because of its psychoactive effect, THC has become the primary distinguishing feature between marijuana and hemp. Marijuana has high concentrations of THC, whereas hemp does not. All cannabis contains at least trace amounts of naturally occurring THC, along with numerous other cannabinoids, though. The law is mostly geared to this distinction. Cannabis varieties with high THC levels are illegal, both federally and in some states. On the other hand (and speaking very generally), plant varieties with low THC levels, pegged at no more than 0.3 percent by federal statute and grown in accordance with a lawful hemp program, are legal.*

Hemp is generally grown for its abundance of cannabidiol. Better known as CBD, this cannabinoid is not psychoactive and is responsible for a majority of the medical benefits associated with cannabis. Because of its almost ubiquitous health properties, even listing the medical issues for which it appears to offer benefits comes off as a snake oil medicine advertisement. Yet for over a decade, numerous studies have been written in peer-reviewed publications about CBD's role in reducing pain, helping to relieve anxiety and PTSD, reducing seizures, as an anti-inflammation agent, and as neuroprotection that can aid victims of concussion, stroke, and even Alzheimer's. Multiple studies have even confirmed that it reduces certain cancer cells. Big Pharma is rapidly developing CBD-based medication. Even the U.S. government holds a patent—number 6,630,507—on the use of non-psychoactive cannabinoids, such as CBD, to protect and insulate the brain from damage or degeneration. Because of the enormous role that CBD plays in health, an entire industry has emerged to deliver CBD to people in the form of tinctures, vaping oils, topical applications, oral solutions, and in food and drink products. And although CBD can be derived from marijuana, its economic impact from this source is limited by marijuana's federal illegal status preventing, among other things, interstate (and international) commerce. However, hemp is legal at the federal level. (This is an oversimplification: hemp's legal status is complex, rapidly evolving, and in some respects "gray." A large part of my practice involves advising my hemp and CBD business clients on how to stay on the correct side of the law.) Being federally legal, hemp is not constrained by the same restrictions imposed on marijuana. This means that hemp-derived CBD can be transported, used, and sold across state and national borders. Numerous interesting legal issues are emerging from this sector, from federal regulatory oversight to banking and finance to marketing and labeling and quality control. But it is clear that hemp, marijuana's relatively unfettered sibling, is poised to overtake the health industry, both in the U.S. and internationally."

Please see below, an email sent to us personally by Rod Kight, following an email we sent seeking his advice and thoughts on Australian CBD Legislation and scheduling restrictions.

Matthew,

I am not overly familiar with Australia's scheduling system and so cannot provide technical advice regarding Parliamentary procedures. What I can say is that cannabidiol (CBD) is not a separately scheduled substance under the laws of the USA or, to my knowledge, any international treaties. It is one of over 100 known chemical constituent components of the cannabis sativa L plant. Unlike tetrahydrocannabinol (THC), which is separately scheduled, CBD is not psychoactive. Ingesting it- orally or topically- does not produce any of the "high" that associated with consumption of THC.

Because cannabis (sometimes referred to as "marijuana") is a scheduled plant, its constituent components are also scheduled unless they are excepted. In the US we have three significant exceptions to the definition of "marijuana", all of which provide for the lawful use, transport, possession, and manufacture of CBD: (1) the stalks and non-germinating seeds of the cannabis plant (21 USC § 802(16)), (2) industrial hemp that is grown according to a State's pilot research program for industrial hemp, and which contains less than 0.3% delta-9 THC on a dry weight basis (7 USC § 5940), and (3) "non-psychoactive" hemp that is lawfully cultivated outside the US (such as in Switzerland, Slovenia, China, Canada, and any number of other countries where hemp cultivation is lawful), (Hemp Industries Association v. DEA).

Given the significant, well-documented, and wide ranging health benefits of CBD (and other non-psychoactive cannabinoids such as CBG, CBD, and a host of terpenes, proteins, etc) and the lack of any significant evidence showing toxicity- even at high doses- government action to ban its use seems either ill-informed or a cynical move to enrich what we in the US call "Big Pharma", by which we mean large multinational pharmaceutical companies that are actively working on cannabinoid based medications. It is in Big Pharma's interest to limit public access to CBD, particularly CBD that is derived naturally from hemp cultivation. While Big Pharma's patented medications have their place, there is no rational reason to limit cultivation of the non-psychoactive hemp plant and its health promoting constituent components, such as CBD.

Industrial/ non-psychoactive hemp is not contrary to the provisions of any treaty. By extension, none of its otherwise non-scheduled constituent components (such as CBD) are contrary to the provisions of any treaties. I would be happy to discuss (in person or via Skype) hemp and CBD with any MP or other government official that is interested in the rapidly growing world hemp market.

Please let me know if I can be of further assistance.

Rod Kight

WORLD ANTI-DOPING AGENCY ALLOWS ATHLETES TO USE CBD

12 Feb 2018

Surprisingly, the World Anti-Doping Agency has rolled back its prohibition on CBD. As of January 2018, Olympic athletes will not be disqualified for using CBD.

The World Anti-Doping Agency - WADA - is a foundation created in 1999 through an initiative led by the International Olympic Committee.

Its mission is to obstruct and monitor the illegal or dubious use of sports-enhancing drugs. Cannabis has long been included in the list of forbidden substances, primarily due to its federal prohibition. This is in spite of cannabis' known therapeutic benefits in regard to muscle recovery, inflammation, and chronic pain management.

This will, however, change as of January 2018. Cannabidiol (CBD) has officially been dropped from the list of controlled substances. Now, top athletes from across the globe need not fear about experimenting with CBD-rich oil extractions, infusions, and edibles.

TIMES ARE CHANGING

When an organisation like WADA openly declares that CBD is ok to use by top athletes in the world for the prestigious Olympic games, you know we are on the cusp of significant change in the fabrics of society.

Governments across the globe will have to sit back and digest this information. How can you legitimately deny an Olympic athlete, or a regular citizen for that matter, a CBD oil extract to treat their muscle recovery pains when the world's top anti-doping agency says it's not dope?

Exert taken from the following Website link :-

<https://www.royalqueenseeds.com/blog-world-anti-doping-agency-allows-athletes-to-use-cbd-n778>

Expert Committee on Drug Dependence

Thirty-ninth Meeting

Geneva, 6-10 November 2017



**World Health
Organization**

Expert Peer Review for Cannabidiol (CBD)

1. Comments based on the review report

a. Evidence on dependence and abuse potential

There are few studies regarding dependence, however, the Pre-Review describes in an animal study that no tolerance developed to CBD at any of the dosages, unlike with THC that was also studied. With regards abuse potential, in an animal administration study there was no indication of self-stimulation and reward activity for CBD. In discrimination studies, CBD did not substitute for THC. In humans, the Pre-Review reports that while the number of studies is limited, the evidence from controlled experimental research indicates that CBD is not associated with abuse potential. CBD was equivalent to placebo and unlike THC in the studies, did not exhibit features of abuse potential. Furthermore, the Pre-Review states study findings suggest that oral CBD does not reduce the reinforcing, physiological, or positive subjective effects of smoked cannabis. There are no case reports of abuse or dependence relating to the use of pure CBD.

b. Risks to individual and society because of misuse

There do not appear to be any instances of misuse by individuals. The PreReview Report states that across a number of controlled and open label trials of the potential therapeutic effects of CBD, it is generally well tolerated, with a good safety profile. No instances of non-fatal or fatal toxicity have been reported, indeed there is no evidence that CBD would produce acute toxic effects.

c. Magnitude of the problem in countries (misuse, illicit production, smuggling etc)

There do not appear to be any instances of misuse, illicit production or smuggling, etc of pure CBD. The Pre-Review describes that there is unsanctioned medical use of CBD based products. These are produced from high CBD content plants and distributed in a variety of forms, including oils and capsules. These products are sold online as unapproved treatments for a variety of disorders including epilepsy, cancer, AIDS/HIV, anxiety, arthritis, pain, and post-traumatic stress disorder (PTSD).

d. Need of the substance for medical (including veterinary) practice

The Pre-Review states that the clinical use of CBD is most advanced in the treatment of epilepsy. In clinical trials, CBD has been demonstrated as an effective treatment for at least some forms of epilepsy, with one pure CBD product currently in Phase III trials. There is also evidence that CBD may be a useful treatment for a number of other medical conditions. However, this research is considerably less advanced than for treatment of epilepsy. For most indications, there is only pre-clinical evidence, while for some there is a combination of pre-clinical and limited clinical evidence. The range of conditions for which CBD has been assessed is diverse, consistent with its various properties. Whilst CBD is present in some nabiximols products, there are no currently authorized pure CBD products but the Review states there are several in development.

e. Need of the substance for other purposes (e.g. industrial)

CBD has no industrial or other use.

f. Measures taken by countries to curb misuse

The Pre-Review Report stated that CBD is controlled (through national legislation either as a named substance or within a product or cannabis) in Australia, Canada, New Zealand, Switzerland, United Kingdom and the USA.

g. Impact if this substance is scheduled

No specific information but it may affect current or future therapeutic applications. CBD is not listed on the WHO Model List of Essential Medicines.

2. Are there absent data that would be determinative for scheduling?

None.

3. Other comments or opinions

None.

4. Expert reviewer's view on scheduling with rationale

CBD is not listed in the schedules of the 1961, 1971 or 1988 United Nations International Drug Control Conventions but CBD is being produced for pharmaceutical purposes as an extract of cannabis. There is no evidence that CBD as a substance is liable to similar abuse

and similar ill-effects as substances in the 1961 or 1971 Conventions (including cannabis and dronabinol (THC)). Nevertheless, the purpose of the pre-review is to determine whether current information justifies an Expert Committee critical review whereby the Committee finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions. As such, as CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), in my view the information presented in the Review Report does not justify a change in this scheduling position and does not justify scheduling of the substance. However, a critical review may be warranted within any review of cannabis extracts and tinctures.