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7/05/18

James Vosper
President AIHA
3 Pattie Place
Woy Woy, NSW 2256

Dear Sir/Madam,

I am writing in response to the invitation to comment on the Consultation (https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-being-referred-june-2018-meetings-accs-acms-and-joint-accsacms).

I write in the capacity of my position as President of the Australian Industrial Hemp Alliance (Registered NSW incorporation Number INC 1500123/ ABN 53 617 534 381). Our organisation is the peak national body representing all aspects of the hemp industry. Our members include farmers, builders, machinery producers, manufacturers and marketers of hemp products. Our objective, in line with the Federal Government, is for Australia to be a world leader in the hemp industry.

This industry, if allowed to flourish has the potential to deliver significant economic benefits and employment, especially in areas currently facing hardship, declining opportunity and an egress of population. This also correlates with areas of indigenous populations, with whom we are in close contact.

More specifically, I am writing regarding the proposed changes to the scheduled status of cannabidiol (CBD) and the application to change the maximum concentration of the cannabidiol from 2% to 1% in Schedule 4 of the Poisons Standard.

This is outlined in the table below (Figure 1) where the proposal has been made on behalf of a "private applicant". Under "Reasons for the proposal" the following is written:-

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 industrial hemp industry has been at great pains to make it clear that THC is separate to hemp and is derived from a different plant subspecies. The inclusion of this sentence suggests that there is a connection between CBD and THC. This is erroneous and serves to propagate the confusion of non-psychotropic CBD with THC.

Figure 1

Cannabidiol and tetrahydrocannabinols (THC)	Substance	Cannabidiol	THC
	CAS number	13956-29-1	1972-08-03
	Alternative names	2-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol (IUPAC)	Dronabinol (INN); (6a*R*,10a*R*)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo(b,d)pyran-1-ol (USPDDN); (-)-(6a*R*,10a*R*)-6,6,9-Trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6*H*-benzo[*c*]chromen-1-ol (IUPAC)
	Applicant	Private applicant	
	Current scheduling	Cannabidiol is in Schedules 4 and 9 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 (link is external) (TGO 93), 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):* *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"*	

AIHA Position

It is our belief that CBD needs less regulations as it is non-toxic and non-addictive. There are many documented studies of CBD that support this. CBD is used globally in treating many conditions, most notably intractable epilepsy (Dravet's Syndrome). There are wider benefits in treating chronic pain and in palliative care for cancer patients.

It is also proving effective in combating the current abuse of opioids, where addiction and death are commonplace. In US states where medicinal cannabis is available prescriptions for opioids have fallen by as much as 25%. (https://www.sciencedaily.com/releases/2018/04/180402202236.htm). This has negative implications for Australia as it is a major supplier to the opioid industry and derives some $300 million per year from the sale of raw materials for drugs. Future export shortfalls can be more than covered by the Australian medicinal cannabis industry.

The World Health Organisation has determined that CBD is safe and that it should not be scheduled (http://www.who.int/features/qa/cannabidiol/en/).

The study, published on December 15th 2017, states:-

"At its November 2017 meeting, the WHO Expert Committee on Drug Dependence (ECDD) concluded that, in its pure state, cannabidiol does not appear to have abuse potential or cause harm. As such, as CBD is not currently a scheduled substance in its own right."

The TGA did have a response to this and published the following on December 15th 2017:-

https://www.tga.gov.au/media-release/tga-recognised-who-findings-cannabidiol-three-years-ago

In this publication the TGA stated the following:-

"The findings of the WHO mirror those made by the TGA almost three years ago. At that time TGA decided to re-classify cannabidiol from being a "prohibited substance" (Schedule 9) to a "prescription medicine" (Schedule 4) in the Poisons Standard."

"The WHO was assessing CBD to determine whether it is psychotropic, addictive and subject to potential abuse. It determined that it is not psychotropic and therefore recommended that it not be 'scheduled' under either of two international treaties - the Single Convention on Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971."

"CBD remains prescription only in Australia because the conditions that it might be used to treat, such as epilepsy, are serious medical conditions and require medical diagnosis and oversight. It is for this reason that cannabidiol is not available 'over the counter."

In view of the acceptance that CBD is not a threat to health, lowering the accepted concentration levels is incongruous.

The World Anti-Doping Agency (WADA) is one of the most stringent organisations in identifying substances that are either harmful or change behaviour. In 2017 WADA removed CBD from the banned list whilst continuing to ban THC. This was in response to that fact that many athletes use CBD as an anti-inflammatory.

https://www.washingtonpost.com/news/early-lead/wp/2017/10/05/while-marijuana-remains-banned-wada-reverses-course-on-hemp-derived-compound-cbd/?utm_term=.bb3442856e10

In conclusion we see no reason why further restrictions should be applied to the scheduling of CBD and trust that the TGA will do what is best for the industrial hemp industry and users of CBD.

It is our recommendation is that this proposed change be denied.

Yours Faithfully,

[redacted]

James Vosper