[redacted]

May 8th, 2018

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 Chief Executive Officer of BOD Australia Limited (ACN 601 225 441). Our organisation is a public company holding a medicinal cannabis import licence. We are actively studying the effects of low THC, high CBD cannabis extracts for use in several medical conditions. Our objective, in line with the Federal Government, is for Australia to be a world leader in the medicinal cannabis 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.

I am writing regarding the proposed changes to the scheduled status of cannabidiols and the application to change the maximum concentration of the 'other cannabinoids' 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*"

It is clear that tetrahydrocannabinol (THC) is separate to cannabidiols 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 compounds with the psychotropic THC.

[redacted]

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 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 (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"*	

BOD's Position

It is our belief that the current CBD regulation is sufficient (if not even too restrictive) as it has been shown to be non-toxic and non-addictive[i]. There are multiple clinical studies of CBD that support its safety[ii]. CBD is used globally in treating numerous conditions, for example, Chemotherapy Induced nausea and Vomiting and Epilepsy[iiiivvvi].

It is also showing promise 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%[vii].

The World Health Organisation has determined that CBD is safe and that it should not be scheduled[viii]. 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

[redacted]

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[ix]:- 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[x].

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

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

Yours Sincerely,

[redacted]

Jo Patterson
Chief Executive Officer

[redacted]

[i] Bergamaschi, M. M. (2011). Safety and Side Effects of Cannabidiol, a Cannabis sativa Constituent. *Current Drug Safety, 6*(4), 1-13.

[ii] Consroe, P. (1991). Controlled Clinical Trial of Cannabidiol in Huntington's Disease. *Pharmacology Biochemistry and Behaviour, 40*, 701-708.

[iii] Geffrey, A. L. (2015). Drug-drug interaction between clobazam and cannabidiol inchildren with refractory epilepsy. *Epilepsia, 56*(8), 1246-1251.

[iv] Devinsky, O. (2017, May). Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. *The New England Journal of Medicine, 376*(21), 2011-2020.

[v] Devinsky, O. (2016). Cannabidiol in patients with treatment-resistant epilepsy: an open-label interventional trial. The Lancet: Neurology, 15(3), 270-278

[vi] Duran, M. (2010, November). Preliminary efficacy and safety of an oromucosal standardized cannabis extract in chemotherapy-induced nausea and vomiting. British Journal of Clinical Pharmacology, 70(5), 1365-2125.

[vii] Science Daily April 2018 (https://www.sciencedaily.com/releases/2018/04/180402202236.htm)

[viii] WHO December 2017: http://www.who.int/features/qa/cannabidiol/en/

[ix] TGA December 2017: https://www.tga.gov.au/media-release/tga-recognised-who-findings-cannabidiol-three-years-ago

[x] Washington Post October 2017: 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