



20 May 2020

ATTENTION: Advisory Committee on Medical Scheduling

Via email: medicines.scheduling@health.gov.au

Consultation: Proposed amendments to the Poisons Standard - ACMS and Joint ACMS/ACCS meetings, June 2020

2.2 Cannabidiol CAS Number 13956-29-1

Dear Committee member,

Industrial Hemp Western Australia Association Inc. (iHempWA) was established by incorporation in 2015 and is the peak state body for industrial hemp matters in Western Australia. 'Industrial hemp' is also considered to include medicinal cannabis and all commercial aspects of the cannabis plant, when produced with < 0.35% THC.

iHempWA collaborate with the WA Hemp Grower's co-op (HempGro) and are a member of the Australian Industrial Hemp Alliance (AIHA) the peak national incorporated body. Late in 2019 we lobbied for urgent Policy and Regulatory reform through the West Australian and Federal Government in relation to the processing and sale of low THC whole plant products and enriched or pure fractions (compounds) of the plant containing less than 0.35% THC in accordance with the Industrial Hemp Act 2004 WA.

Cannabidiol (CBD) is a non-psychoactive cannabinoid derived from the plant Cannabis Sativa and has been the subject of much discussion and marketing in recent years. There is great interest in its use either as a dietary supplement or as an over-the-counter product for a wide range of health benefits including pain management, relaxation and stress relief, sleep aid, antidepressant, antioxidant, anti-inflammatory, neuroprotective, and other indications.

Typical doses of CBD that have been used for seizure disorders and psychotic conditions are in the range of 10–20 mg/kg/day, with the higher dose being most commonly used. At these doses, the most common adverse events have included somnolence, diarrhea, decreased appetite, fatigue, and, less frequently, elevated serum aminotransferases.

Our Association recommends removing Cannabidiol (CBD) from the SUSMP, as it is our understanding that the primary purpose of the Poisons Standard is to list compounds / substances which have a determined lethal dosage (LD) and recently published clinical studies have confirmed that a LD for CBD does not exist.

iHempWA submits that a rescheduling of CBD from Schedule 4 to Schedule 3 does not go far enough and it is our opinion that industrial hemp produce, compliant with THC limits under 1%, from which CBD dominant foods can be produced should only be regulated through Food Standards (FSANZ) and not the Poisons Standard. Cannabidiol should be de-scheduled, readily available, and affordable. Australia has the capacity to produce large quantities of CBD from industrial hemp for the domestic and export markets.

Current regulatory framework is stifling the growth of the Australian hemp industry, predominantly

Chairperson: Georgina Wilkinson
Lot 2/5962 Caves Rd
Margaret River WA 6285
Email: general@hempco.net.au

Industrial Hemp Western Australia Association Inc.
Registered WA incorporation Number: A1019234F
ABN: 83228554107
Registered office: 3 Zamia Place
Margaret River WA 6285





due to the restrictions relating to the utilisation of the whole-plant, resulting in our industry missing out on a significant economic opportunity for the Australian agricultural sector. We are continuing to lag far behind our global competition, due to over-regulation relating to produce from industrial hemp. Products made from whole-plant industrial hemp are readily available in the US, Canada, EU and a growing number of Asian and African countries – taking advantage of the burgeoning global CBD market-place. Australian high standards relating to food safety will ensure compliant and safe production of a commodity in high global demand, where Australian produce presents a major opportunity for export markets, resulting in a significant economic impact in this emerging market segment.

The de-scheduling of CBD will provide a stimulus to the Australian economy as it will give a significant return to the rural communities where the industrial hemp is cultivated and processed. This will result in an economic flow-on effect through processing, packaging, transport, marketing, and sales. This deregulation will also result in a stimulus that benefits the construction industry, where facilities are built from the ground up, or where existing facilities are remodeled or repurposed.

The Australian economy will benefit from a healthier population, especially in the area of mental health and general well-being. These impacts are important now and will grow in importance due to the COVID-19 pandemic and the aftermath from it.

The Australian Government has many schemes in place to respond to the current pandemic and its effects on our population and economy. Many of these actions require significant investment, ongoing complex management and administration processes. It is absolutely certain that de-scheduling of CBD will have positive economic outcomes, as it will be felt in rural areas where cultivation takes place and new employment will be generated. This will require no direct investment from the government and will be perceived as a proactive and positive action by the public.

Our association, as a potential industry participant in the cultivation and supply for manufacture of industrial hemp produce, has direct commercial interest in the de-scheduling of CBD, as it will allow us to fund our association's vision is to establish, develop and support a sustainable and prosperous hemp industry for Western Australia, which in turn will support the recreation of other local and domestic sectors; processing, manufacturing, retail, export and industries; paper, timber, textile; food and nutrition; providing sustainable employment and attracting investment.

The currently regulatory framework under which we operate is extremely restrictive and commercially unviable, as we are not able to produce CBD products for domestic human consumption and the descheduling of CBD will provide agricultural companies like ours, the opportunity to generate another revenue stream at farm-gate.

Retaining CBD on the Poisons Standard (even if re-scheduled from 4 to 3 or 2) will result in the continued exclusivity to operate in this market segment by a very limited number of Medical Cannabis licence holders, who within the last 4 years, since the legalisation of Medical Cannabis in October 2016 have demonstrated their inability to bring to the domestic market affordable Australian grown products. The recent Senate enquiry, which resulted in the consultations on Cannabidiol in which we are participating as industry stakeholders, confirmed the dysfunctionality of the Medical Cannabis Industry.

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Further, the Report on the Review into the 2016 Medicinal Cannabis amendments to the Narcotic Drugs Act 1967, by Prof John McMillan not only addressed and tabled recommendations to the Medical Cannabis Scheme, but specifically addressed the removal of CBD as a scheduled and controlled substance.

CBD is safe, as confirmed by TGA's own publication in April 2020 on the "Safety of low dose cannabidiol" and in the published review by SJ Stohs and SD Ray on 11/05/2020 "Is cannabidiol hepatotoxic or hepatoprotective"

<https://doi.org/10.1177/2397847320922944>

iHempWA submits that regulating CBD as other herbal medicines and complementary medicines are regulated will substantially increase its access and reduce costs to the consumer.

iHempWA submits that regulating CBD as a complementary medicine will allow its prescription by other qualified healthcare practitioners such as western herbal medicine practitioners and registered Chinese herbal medicine practitioners, consistent with their scope of practice, and further increase access to patients.

iHempWA submits that the example of legalisation of hemp foods in Australia in November 2017 and the subsequent absence of **any** negative impacts arising therefrom should be taken into account in considering the application. It took some 17 years' of applications and lobbying and time, energy and money to achieve a good outcome in legalising hemp foods, a product made from the natural cannabis plant.

In summary, iHempWA representing its members and all Western Australian hemp industry stakeholders have significant potential commercial interest in the descheduling of CBD and as such, based on the arguments raised herewith, as well as within submissions by the AIHA, iHempWA **supports** the **Proposed amendments to the Poisons Standard**.

Yet, iHempWA reserve **concerns**; that this down scheduling event will not equate to increased patient access to safe, effective phytocannabinoid products and will not create jobs or stimulate the local / domestic economy; that this down scheduling is merely another bureaucratic façade that will financially benefit pharmacies and their pharmaceutical suppliers with potential to harm patients / consumers.

<https://uk.formulaswiss.com/blogs/cannabis-cbd/synthetic-vs-natural-cbd-which-is-a-better-option>

<https://www.healthline.com/nutrition/cbd-oil-benefits>

Additional Notes:

It appears the **Safety of low dose cannabidiol V1.0 April 2020** (review) assumes CBD to be an effective complementary medicine, as it focused on safety and therefore did not look at the efficacy of low dose CBD.

It appears that the list of common side effects presented under Safety and adverse effects of review may be exacerbated when using the synthetic CBD and reduced when using broad spectrum plant based products.

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It appears the review found plant based CBD isolate or synthetic CBD enantiomer had potential to harm patients.

It appears the review found the use of synthetic CBD may have psychoactive potential.

It appears the review, sighting just one study, found the existence of an entourage effect remains disputed.

It appears the review concludes that the safety profile is based on cannabidiol having low affinity for the CB1 and CB2 receptors.

In November 2017 Cannabidiol (CBD) was declared a poison by the Therapeutic Goods Administration and listed as a Schedule 4 & 8 Poison depending upon the THC concentrations, based on reference to narcotics as opposed to safety. These unfair and illogical Federal TGA poison restrictions ignore the significant investments from the non-medical hemp industry and in our opinion, rely upon overseas pharmaceutical companies influence over Federal Health policy. (1)

The World Health Organisation (WHO) recently made a recommendation to the UN Secretary General that 'preparations considered to be pure cannabidiol should not be scheduled with the International Drug Control Conventions at all' and appears to be moving to take it off the Drug Schedule. Noting that Cannabidiol "does not have psychoactive properties and has no potential for abuse and not potential to produce dependence. It does not have significant ill-effects," (2)

We understand that on the week of the 15 November both the Federal Health Department and the Office of Drug control discussed and voted on 26 recommendations around legislation of Medicinal Cannabis and CBD oil. The only recommendation which was not agreed upon was that CBD oil be allowed to be non-regulated however, synthetic CBD will not be regulated.

"Stage 1 – key recommendations:

Stage 1 implements Recommendation 2

- 1. The relevant amendment will exclude cannabidiol (CBD)(including all isomers and salts) from being prescribed under section 4A of the ND Regulation as a drug for purpose of the ND Act.*
- 2. In practical effect, there will be no change to CBD from cannabis plants being regulated under the ND Act, but synthetic CBD will not be regulated under the ND Act."*

Removing the CBD restrictions will underwrite our members use of the stalk for building and fibre markets that need a full whole plant approach. The benefits to CBD reform in Australia and WA are three fold based on a triple bottom line benefit ;

- Economic – Tax benefits. As well as a wide range of taxes and flow on multiplier impacts on State and Federal taxes, WA could learn from the USA tax revenue systems that could provide specific additional taxes on CBD extracts.
- Environment – The McGowan Government is currently reviewing an ambitious 2050 zero emissions policy. Cannabis sativa is one of the highest carbon fixers per hectare when a whole plant approach is taken by locking in the carbon grown via the soil and building products such as hempcrete in line with UN Sustainable Development Goals to mitigate and adapt to climate change.
- Social – CBD has a wide range of benefits in preventative health for a healthier community.





With respect



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