



21 May 2020

ATTENTION: Advisory Committee on Medical Scheduling

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

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

2.2 Cannabidiol CAS Number 13956-29-1

Dear Sirs,

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.

Several animal studies have raised questions regarding the potential hepatotoxicity of CBD, with a number of animal studies having demonstrated that CBD is hepatoprotective.

CBD safe and free of serious adverse events, including hepatotoxicity, at the doses that are commonly and widely used in dietary supplements and foods. These supplements and food-related doses are typically in the range of 25–100 mg/day as compared to doses of approximately 1000–1400 mg/day for a 70 kg human for neurological disorders.

Our company Hemp Fields Pty Ltd **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.

It is our submission 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 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 de-regulation will also result in a stimulus that benefits the construction industry, where facilities are built from the ground up, or where existing facilities are remodelled 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 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 company Hemp Fields Pty Ltd, as major 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 invest further resources into the creation of jobs and expanding our capacity to produce high-value plants for CBD production for the domestic and export markets.

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 de-scheduling 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.

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>)

In summary, our company as an industry stakeholder has significant commercial interest in the de-scheduling of CBD and as such, based on the arguments raised herewith, as well as within submissions by the AIHA and NSW IHA, which we fully support, we urge the Advisory Committee on Medical Scheduling to recommend the de-scheduling of Cannabidiol from the SUSMP.

Regards

[Redacted signature]

[Redacted name]

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