



21st May 2020

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

2.2 Cannabidiol CAS Number 13956-29-1

ATTENTION: Advisory Committee on Medical Scheduling - medicines.scheduling@health.gov.au

To whom it may concern,

I am writing on behalf of the Australian CBD community as lead administrator and co-founder of CBD Reviews Australia. I am a member of the Australian Industrial Hemp Alliance (AIHA) and Medical Cannabis Council (MCC). With close to 5000 members in its first year of operating, CBD Reviews Australia was created to stop scammers in the CBD industry from taking advantage of sick and vulnerable people.

Members of the community support the application (item 2.2 in the Public Notice of 17 April 2020) to remove and de-schedule CBD products (in which 98% or greater of the cannabinoid content is CBD and where the upper limit to THC content is 0.2%) from the SUSMP. It should be regulated as a complementary medicine in the same way that other plant medicines are regulated in Australia.

Most people in the community use CBD in some shape or form for a multitude of health reasons. Whether it is for themselves or that of a loved one – human or animal. In total, **there are at least 30,000 people in various communities who are involved with CBD** on some level. These are just the visible communities. Majority are users with medical issues or have family and friends who are ill. This does not include those who do not have social media or access to digital communications. This conservative estimation is testament to the efficacy of CBD products for conditions ranging from anxiety to epilepsy – epilepsy being an ailment with proven clinical research that demonstrates how CBD can save lives. Not to mention the obvious demand and business opportunities.

Although regulation is necessary, it needs to be balanced. The current model is not working. Hundreds of thousands of Australians are unable to access or afford what is on the legal market.

The recent Senate Inquiry into current barriers to patient access to medicinal cannabis (CBD an important part of the inquiry) clearly demonstrated that **consumers and industry groups want cheaper and more readily accessible CBD**. It also highlighted how **industry has a great desire to develop and grow a new part of the economy**. It is positive that the Therapeutic Goods Administration (TGA) is consulting the public on this after the Senates recommendations. For that, we are thankful.

However, I believe the proposal of rescheduling CBD products from Schedule 4 to Schedule 3 (item 2.5 in the Public Notice of 24 April 2020) is not ideal and will not change much if anything regarding accessibility and affordability of CBD.

The proposed requirements ('Registered' AUST R) to get a product to market will likely mean products are going to continue to be expensive. Only a handful of entities will be able to meet the requirements. The lack of competition will mean more pain and unnecessary expenditure for everyday Australians.

Given the proof supplied in the proposed application of CBD being beneficial, its good safety profile and low risk, it should be regulated as a complementary medicine in the same way other plant medicines (herbal medicines) are regulated in Australia. *It also has exceptionally low abuse potential. No major adverse reactions or deaths have been attributed to CBD in clinical research. No negative reports have been made to the TGA.* (WHO 2018a; TGA 2017).

"The WHO 2018 report states:

'...CBD does not produce the effects that are typically seen with cannabinoids such as THC. It also failed to produce significant effects in a human study of abuse potential discussed below. [34] Across a number of controlled and open label trials CBD of the potential therapeutic effects of CBD it is generally well tolerated, with a good safety profile. [39, 53]' (WHO 2018a)."

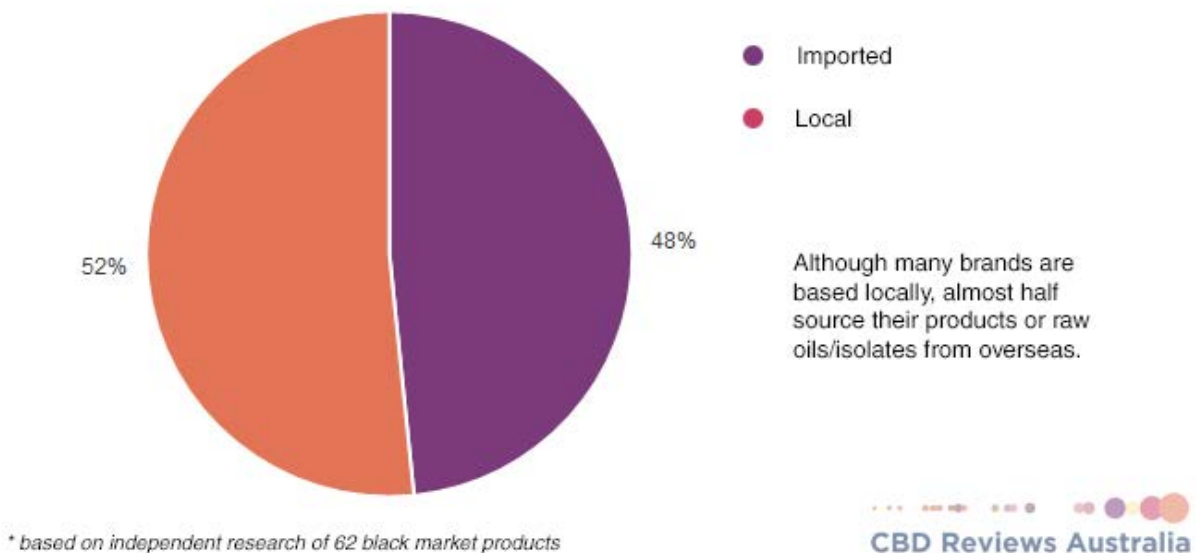
Regulation of CBD as a complementary medicine will allow its prescription by other qualified healthcare practitioners such as western herbal medicine practitioners and registered Chinese herbal medicine practitioners, consistent with their scope of practice, and further increase access to patients.

Regulation of CBD as a complementary medicine would allow the same level of access to CBD products as is enjoyed in many western countries including the US and countries within Europe where hemp-derived CBD products may be purchased over the counter or online. *With the bonus of consumers having the option to get professional guidance when purchasing CBD in Australia.*

Concerns about potential drug-CBD interactions can be handled effectively through limiting the amount of CBD able to be sold in a month's supply and the inclusion of appropriate warning labels. *Additional support information can be made available through a new Australian Government website.*

Continuing the current pathway or down scheduling from Schedule 4 to Schedule 3 will likely mean black market CBD products with no quality assurance shall keep being acquired online from overseas. This impacts the growth of Australian Hemp and Cannabis industries.

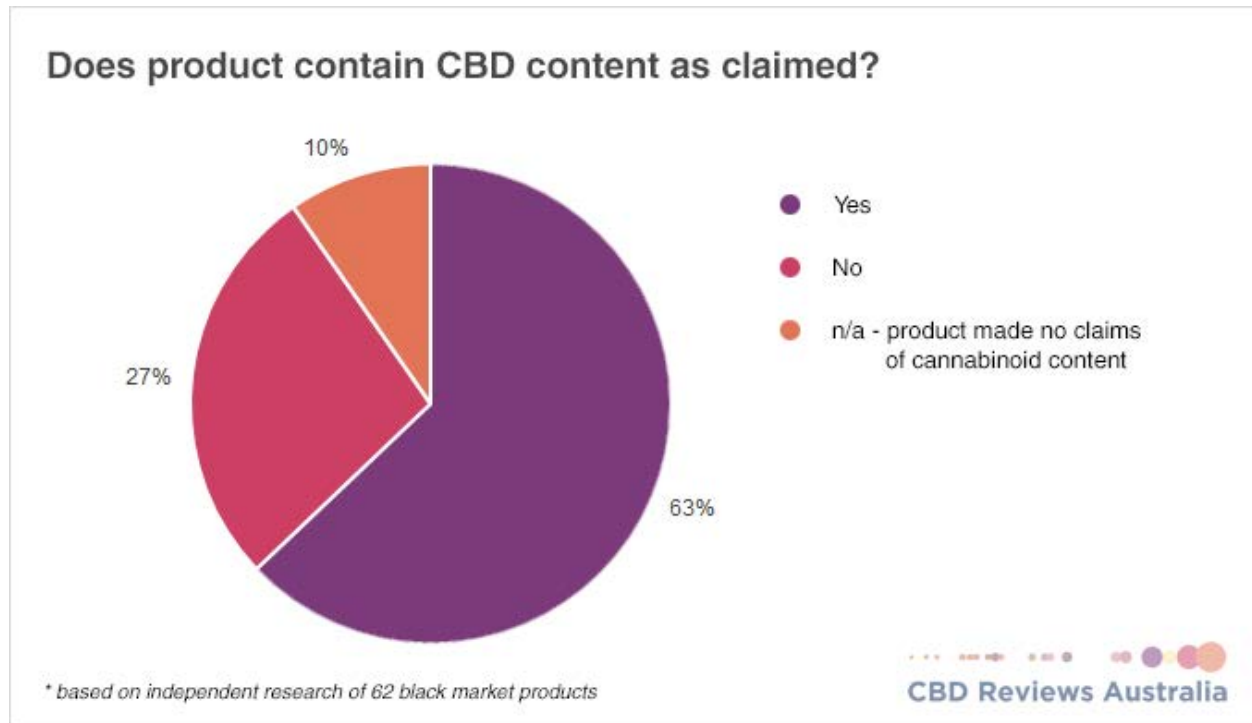
Origin of CBD production



Black market CBD products will also continue to be obtained locally. Accessing CBD products on the black market does not involve a multi-step process that is cost prohibitive to many in comparison. It does not require the expenditure of time waiting for approvals. Time that is valuable for those in need. Consumers can readily access CBD online or in some retail stores and get a product in their hands in 24 hours or less. In comparison, the current process is laborious and requires long wait times. On average 7-10 days before receiving a product in hand. This is the reality of the current Australian landscape for CBD.

A host of black-market sellers mark up their imported CBD product by over 100%. In some cases, by over 500%. Examples can be provided on request. Several black-market sellers sell plain olive oil with no cannabinoids present to unsuspecting consumers. These unconscionable acts hurt people that are seeking helping and are unable to get it due to the current system and barriers in place. The profits go to individuals that have no interest in consumer health concerns or supporting the Australian Hemp and Cannabis industry. The Australian Government is likely missing out on potential tax revenue from the hundreds, possibly thousands of sellers out there.

If CBD is not de-scheduled and regulated *appropriately*, Australian consumers will continue to put their health in danger purchasing unregulated, misrepresented, low quality and potentially toxic CBD products – *because they have no other affordable and conveniently accessible option.*



Schedule 3 Pharmacist Only (over the counter) availability of CBD products will not curb the easy access to CBD online. Nor will it eliminate unscrupulous individuals and businesses as their products will still be easier to access. Many people with medical issues are unable to physically visit a pharmacy counter and prefer to order online and have quick delivery.

Australian consumers want easy, affordable access to high quality tested CBD products. Removal and de-scheduling of CBD products (in which 98% or greater of the cannabinoid content is CBD and where the upper limit to THC content is 0.2%) from the SUSMP is the ideal way forward. **The benefits for individuals, industry and the government far outweigh the negatives.**

Sincerely,

Steven Ng
Co-Founder and Lead Administrator
CBD Reviews Australia