AiO

AIO Unlimited

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ATTN: Therapeutic Goods Administration Expert Advisory Committee

22 May 2020

Melbourne, Victoria

Dear Advisory Committee,

I, Duncan Bruce on behalf of AIO Unlimited, am writing in response to the safety of low dose cannabidiol report dated April 2020. With this letter I would like to say that myself and the organisation I represent support the proposal that low dose 60mg per day CBD should be down scheduled to Schedule 3 of the Therapeutic Goods Act.

We believe that increasing availability and ease of access for this natural medicine will benefit the Australian population and health system. It has been shown through decades of research on how the endocannabinoid and overall human system benefits from CBD.

In addition to giving support of the proposal, I believe that we need to address the processes and systems by which consumers can get access to the medicine in the most effective way. To that extent, at the end of this submission, I have written about my personal experience of acquiring CBD oil via our medical system.

The high cost and difficulty of access disincentivises patients from accessing a medicine which has demonstrated clear healthcare benefits, with low risk and minimal side effects compared to other pharmaceutical solutions available to them through their doctor. Public health will improve when the general public has simplified access to CBD for a range of common ailments which do not require medical supervision. These include sleep disorders, anxiety, chronic pain and post-traumatic stress disorder, which are all increasing in prominence among the general population.

Moreover, if access is simplified, demand will increase, driving the price of CBD down. This will benefit both the end consumer and the health system at large, as more competitors enter the market the quality is driven up, whilst economies of scale work to ensure better product at a lower cost. On a consumer level, should CBD become reclassified to schedule 3, consumers would not have had to spend money on doctors appointments, application fees for forms, driving 45 minutes from my home to collect the product or monitoring appointments each month.

We would estimate that the savings would amount to close to $700 for the first 3 months of treatment compared to what it costs to access the medicine when classified as a schedule 4 drug. Not to mention the time savings and the fact that the process alone is enough to put most people off even starting to try to access CBD in Australia at the moment.

Furthermore, currently when a consumer receives their CBD under the schedule 4, there is no:

- information or warnings,
- contraindications
- drowsiness safety advice
- product ingredients
- clear lack of product information and
- Consumer Medicine information.

Under schedule 3 status, this would be required by law to include more transparency of ingredients and better packaging for the end consumer. International experience suggests that these benefits will flow on to the general population.

Let us for a moment compare Australia's legislation on CBD with other countries such as Canada, the Netherlands, the UK and the USA; where CBD is available over the counter. These countries have clearly evaluated the benefits as outweighing the risks to public health, and it is time that Australia matched their scheduling.

Schedule 3 provides an appropriate balance between increasing distribution of CBD to more patients whilst still maintaining professional healthcare advice at the point of sale, thereby minimising any risks of potential drug-drug interactions. Section 52E of the *Therapeutic Goods Act 1989*; Addresses areas of risk when deciding appropriate availability of any drug.

From the report we can see that safety aspects of CBD have been thoroughly examined, and measures to limit adverse reactions and contraindications can be managed by clear labelling and warnings such as 'may cause drowsiness when driving'.

In terms of risk of misuse, this has also been addressed as being negligible at such a low dose as 60mg/day. While this dose may not be suitable to treat conditions such as epilepsy, which requires higher amounts of CBD each day, this does mean that the consumer purchasing a schedule 3 CBD medicine is able to identify and manage the condition without professional health management and therefore the chance of them confusing their condition with other conditions is very small.

Duncan Bruce - Personal Experience

I received my medical prescription for cannabidiol after being subject to workplace bullying and being diagnosed with post-traumatic stress disorder. My general practitioner was completely unaware of the potential medical uses and applications of medical cannabis and had not been educated on the endocannabinoid system. Subsequent to presenting the general practitioner with efficacy data and studies on the use of cannabidiol for my condition, a referral was made to a private cannabis access clinic.

The private Cannabis Access Clinic billed

$200 for an initial 15 min telehealth consultation

$250 administration fee to fill in a 1-page T.G.A application form

$80 for each subsequent 1o min telehealth appointment for prescribing the product

3 x $80 monthly follow up appointments for monitoring while taking the product.

(Not covered by Medicare or the Pharmaceutical Benefits Scheme)

Timeframe

2 weeks for Referral process from G.P to the Cannabis Clinic
2 weeks to book initial appointment with the Cannabis Clinic

- 1 week for the T.G.A to approve the application
- 2 weeks to be dispensed from a pharmacy located forty-five minutes' drive from my location

The Pre-authorisation was granted from the T.G.A and the private clinic prescribed an imported Canadian cannabidiol product. The certificate of analysis for the product indicated that the product contained only 91% of the active ingredient indicated on the label. The cost of the product was $375 for 25mls of CBD oil (25 days supply of medicine).

From the first time that the General Practitioner was approached about the treatment to receiving the first dose, was 7 weeks at a cost of $1075 in total including one unit of medicine, equivalent to a weeks salary. For each subsequent 1o minute telehealth appointment, a charge of $80 was incurred for a change of product, this occurred three times in order to find the product that was most effective.

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In conclusion the net public health benefit of increased availability for the consumer of reclassifying CBD as schedule 3 clearly outweighs the potential risks. CBD is a treatment which individuals have had to advocate for their own health to obtain, at the mercy of the decisions of Doctors who are working in a system which has not educated them on the endocannabinoid system and which has them working under the pressure, influence and expectation of big pharmaceutical companies.

It is time that patients have safe, reliable, access to medical cannabis and the first step is the down scheduling of Cannabidiol which has had an incredibly positive impact on my live and many lives of those patients who are lucky enough to have had the resources and determination to struggle against a system which has limited and restricted their access to a drug which has an incredibly safe and tolerable profile.

Kind Regards,

[redacted]

Duncan Bruce

Manager

AiO Unlimited

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