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Submission regarding proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #25

as outlined in the Public Notice of 24 April 2020 (item 2.5)

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1.0 About FreshLeaf Analytics

FreshLeaf Analytics, a division of Southern Cannabis Holdings, is a professional services firm providing market intelligence and strategic consulting to international and domestic medical cannabis companies.

FreshLeaf Analytics has deep subject matter expertise regarding patient access in Australia including patient access pathways and forecasts; acquisition and attrition rates; treatment practices and doctor/patient behaviour; product availability and pricing, and medical cannabis policy.

We regularly speak with patients, doctors, regulators and industry members about their needs and challenges and are well placed to provide input to these proposed changes to the SUSMP.

2.0 Executive summary

- We support the delegate initiated proposal as outlined in the Public Notice of 24 April 2020 (item 2.5) to make low-dose CBD available as a Schedule 3 medicine
- Illicit CBD use is already widespread in the Australian community
- These products can be harmful and regulated products should be made available to subvert the illicit market
- Amending the SUSMP will not, in and of itself, be sufficient to subvert the illicit market
- The TGA should develop an industry communication and support program to ensure that companies have a viable path towards S3 drug registration
- If these changes are implemented and products are made available to Australians, we expect this product category to generate at least $200 million in domestic sales per annum

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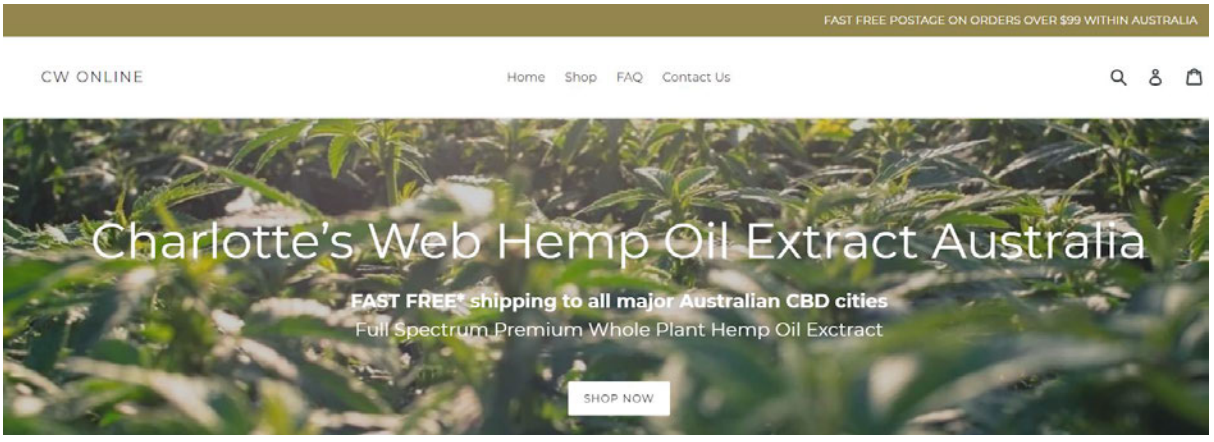
3.0 Illicit unregulated CBD consumption is widespread and poses a public health risk

In the United States, where semi-regulated CBD products have only been recently legalised for retail sale and consumption, at least 14% of the population have used CBD products[1]. In the United Kingdom, where CBD products exploiting legal grey areas are available for retail sale, at least 9% of the population have used CBD products[2].

Despite CBD only being lawfully available in Australia as a prescription medicine or controlled substance, illicit use of unregulated CBD is likely widespread. We estimate that ~3-5% of the Australian population have already used an illicit unregulated CBD product. Some of these products are supplied from local illicit cultivators, but the majority of illicit unregulated CBD products used by Australians are likely imported from overseas.

Illicit CBD suppliers can easily construct Australian-targetted websites where Australians can purchase illicit unregulated cannabis extracts sent through the post to people's homes. These products may be shipped from any number of countries with lax hemp/CBD regulations including the USA. For example, here is a website that appears on the first page of a Google search for "buy CBD Australia":

https://cwcbdoil.com.au/



[1]https://news.gallup.com/poll/263147/americans-say-cbd-products.aspx
[2]https://yougov.co.uk/topics/health/articles-reports/2019/10/18/quarter-britons-tempted-cannabis-extract-products

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Many consumers may not even be aware they are purchasing illicit unregulated products. In the UK, studies have found that illicit unregulated CBD products can be inaccurately labelled and contain THC and alcohol[3]. This presents a public health risk that can be addressed through allowing access to legal regulated CBD products without a prescription.

4.0 Legalisation without real-world access increases illicit demand

From a public health perspective, creating a new Schedule 3 entry for low-dose CBD without taking the steps necessary to actually facilitate access to these products would be counterproductive.

A good example of this is the formal legalisation of Schedule 8 cannabis medicines in 2016. The SUSMP was amended and Australians expected that amendment to produce a certain outcome regarding the availability of those medicines. But patient access regulation and administration then required extensive and ongoing amendments in order to meet community expectations[4].

And the community was not shy about publicly voicing frustrations. A general perception developed that “the government” hadn’t really wanted to “legalise” medical cannabis and were dragging their feet while thousands experienced unnecessary suffering and hardship. Thanks to ongoing lobbying the media frequently covered these stories. This created a combination of sudden and immense public interest on one hand and, on the other, a framework not set up to facilitate the scale of access expected by the public.

When the public perceives the government has “legalised” a product, but they are unable to actually purchase and consume that product, they will be emboldened to seek out illicit products instead. In their eyes it’s already legal, and if they can’t buy it from a shop, why shouldn’t they buy it online instead?

[3]https://www.liebertpub.com/doi/full/10.1089/CAN.2019.0078
[4]https://law.unimelb.edu.au/__data/assets/pdf_file/0010/3214864/Gleeson-432-Advance.pdf

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5.0 The proposed amendments are not sufficient to facilitate access

For low-dose CBD products to be made available as Schedule 3 medicines, we understand that product sponsors will be required to demonstrate their product is effective for the treatment of a specific indication.

Despite the Department of Health claiming that CBD in doses of up to 1mg/kg/day "has possible utility in the management of chronic and generalised pain of broad aetiologies through both systemic and localised administration and in anxiety and insomnia"[5], there have been no double-blind placebo-controlled clinical trials demonstrating that CBD is effective in treating anything at those doses.

As a commercial consulting and data analytics company, we are not in a position to hypothesize about the potential efficacy of low-dose CBD. What we do know is that the few published placebo-controlled RCTs involving CBD at these low doses have been unable to demonstrate that CBD is more effective than placebo.

If the standard of evidence required to register a CBD product and make it available as a Schedule 3 medicine is a double-blind RCT with statistically significant proof of efficacy, it seems unlikely that we will see any such products enter the market, at least for several years.

Since 2016, no new S4 or S8 medicinal cannabis products have been registered on the ARTG. But the community expectation that medicinal cannabis products be made available via prescription has been partially met by streamlining and normalising access to unapproved medicines through the Special Access and Authorised Prescriber Schemes.

It may transpire that Schedule 3 CBD products experience a similar regulatory "pressure release valve" for community demands by normalising access to compounded preparations. This could create additional unintended consequences.

If the SUSMP is amended as proposed, it will generate significant community and media interest. Hundreds of thousands of people will suddenly believe they should be able to

[5]https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf

access low-dose CBD products behind-the-counter at pharmacies. If they find they cannot purchase these products from pharmacies, they will purchase illicit unregulated products online instead.

6.0 We support the proposed amendments but drug sponsors will require clarity and guidance

We agree with the assessment made by the Department of Health that CBD in low doses is safe and should be captured in Schedule 3 of the SUSMP.

However, we anticipate that this amendment to the schedule alone will not be sufficient to facilitate access to these products as intended. In fact we expect that, in the absence of some kind of industry support, these proposed changes will lead perversely to a significant increase in the number of Australians accessing illicit unregulated CBD products online.

We believe it would be prudent for the TGA to hold public consultations with the medicinal cannabis industry to clarify what is expected from ARTG submissions for Schedule 3 CBD products, and to better understand the commercial capabilities and intentions of industry members. Specific guidance should be developed for industry members and opportunities for abbreviated submissions should be explored.

The objective of the proposed amendment should not be narrowly confined to a change in legislation. This process should be considered holistically and with the wellbeing of Australian consumers font of mind.

7.0 If products are made available, low-dose CBD could generate $200 million in sales per annum

In June 2019, the retail CBD market in the UK was estimated to be worth £300 million[6]. In August 2019, 9% of the population was estimated to have taken a CBD product[7]. If we translate that per-capita to Australia and assume similar market penetration and expenditure,

[6]https://www.thecmcuk.org/cbd-market-study
[7]https://yougov.co.uk/topics/health/articles-reports/2019/10/18/quarter-britons-tempted-cannabis-extract-products

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that would be a $200 million market. This is roughly equivalent to the size of the fish oil market in Australia[8].

However, should S3 CBD products get ARTG registration, international sales of those products would massively dwarf domestic revenues. Low-dose CBD products are popular and widely consumed in North America and Europe. This demand is currently being met by essentially unregulated products with limited quality and safety guarantees. A TGA-approved CBD product suitable for retail sale would likely be very commercially successful.

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22/5/20 [redacted]

[8]https://www.sbs.com.au/food/article/2017/03/09/you-probably-need-more-fish-oils-pill-or-food-best-option