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CA Clinics

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)



1.0 About CA Clinics

CA Clinics, a division of Southern Cannabis Holdings, is a national medical clinic network supporting doctors who wish to prescribe medicinal cannabis as an adjunct therapy.

CA Clinics operate on a referral basis where we manage the patient from initial assessment, regulatory application and approval, prescribing, ongoing patient monitoring and medication adjustment, GP updates and patient welfare surveys.

We are in a unique position where we regularly engage with all participants in the industry, patients, doctors, specialists, regulators, and product providers. This gives us a broad perspective and insight into the requirements and usage patterns of looking for access to and using medicinal cannabis in Australia, including CBD.

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 (up to 60 mg per day) 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
- Higher doses should continue to require medical support especially given they are often prescribed with THC medications and form part of broader treatment plan
- We believe the proposed amendments will:
 - o Further legitimise the use of medicinal cannabis as a treatment option
 - Lower medication costs for many people
 - o Improve the speed of accessing low-dose medication



3.0 Use of medicinal cannabis as a treatment option

At CA Clinics we have treated thousands of patients using medicinal cannabis treatments. We strongly believe that there are medical benefits for the use of medicinal cannabis as a treatment option. However, a tiered approach to access should be considered based on dosage and product types.

- 1. Low dose CBD (<60mg per day)
- 2. Higher dose CBD (>60mg per day)
- 3. THC medications

Low dose CBD

Given the relatively low toxicity and general safety of CBD we consider that low dosage is appropriate for Schedule 3 categorisation and concur that a threshold of 60mg per day is appropriate.

Other medicinal cannabis products

Beyond the suggested definition of low dose CBD, we believe that other medicinal cannabis medications should continue to be accessed via doctor prescription as part of a treatment plan.

Our experience indicates that many patients typically:

- Have complex case histories with co-morbidities
- Are receiving medication as part of a broader holistic treatment plan with interactions between a variety of medications and health care professionals
- Need managed titration of dosing to manage outcomes, costs, and side effects, especially at higher dosages
- Are prescribed a combination of CBD and THC products dependant on factors such as indications and work requirements

As such, these medications are best controlled via a doctor and any relevant approval processes. By limiting the daily dose, we expect that this would mitigate associated risks, with no real abuse potential for CBD.



4.0 Removing barriers to access

The opportunity exists to streamline the process for people looking for CBD as a treatment option, thereby reducing barriers to access and reducing economic costs.

For simple cases it broadens treatment options available for patients where they would not meet the category of "treatment of last resort". Access to low-dose CBD via pharmacies would reduce access bottlenecks where treating doctor and TGA support is currently required. Removing the necessity for a doctor consultation would further reduce patient costs and allow patients to proactively assess the efficacy of low-dose CBD before considering if higher doses or other product types might be more suitable.

Introducing low-dose CBD to the mainstream market will likely contribute towards greater acceptance of medicinal cannabis medications, potentially reducing the stigma about its broader medicinal use.

5.0 Concerns

As these products become more mainstream, our key concerns relate to the quality and consistency of the product and the impact on consumer experience. This can be best managed through facilitating the ARTG registration of low-dose CBD products, which would have to meet quality and labelling standards. We note that, in the absence of such product registrations, patients may seek out illicit unregulated products, or compounded preparations. In addition, we would like to see measures in place to stop consumers circumventing the system by buying large quantities of low-dose CBD to achieve higher dosages without visiting a doctor.



Andrew Glover General Manager 22/5/2020