Submission to the 'Consultation: Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #25: Cannabidiol'

22 May 2020

Pharm-a-Care Laboratories Pty Ltd.

About Pharm-a-Care

At Pharm-a-Care, we are dedicated to enriching people's lives through health and wellness. We want to inspire Australians to be the best, healthiest and happiest they can be. Whether we are making a vitamin, protein powder, deodorant, skincare moisturiser, or healthy superfood snack, it all comes down to creating the best and most effective products under trusted brands that are household names. We strive to be different, innovative, and surprising – but to always make a positive difference to people's lives, every day.

Pharm-a-Care is 100% Australian and family-owned. And while we have offices globally, and our products are in high demand all around the world, our soul is Australian, our quality is Australian, and our spirit of honesty, hard work and entrepreneurial drive is Australian.

Pharm-a-Care is a leading market supplier of a number of brands of consumer and therapeutic goods both in the domestic and international markets. These product offerings range across various categories from FMCG, foods, medical devices, cosmetics, Registered medicines, and Listed complementary medicines.

Pharm-a-Care's Response to the Proposals to Amend Scheduled Access to Cannabidiol (CBD)

Pharm-a-Care supports down-scheduling of cannabidiol ('CBD') in Australia as an essential measure to reduce community barriers to accessing medicinal cannabis.

Reducing barriers to access of CBD would support many Australians with mild health conditions by improving their overall wellbeing, reduce the overhead cost of generation of prescription for these medicines, whilst still maintaining high-quality and safe CBD products. We encourage access to high quality, safe and cost-effective CBD products.

As evident from the published literature, CBD in certain preparations has an acceptable safety profile for an over-the-counter (OTC) medicine, including minimal drug interactions, and is able to alleviate and treat certain conditions that are considered to be suitable for a pharmacist to manage.

Further, CBD appears to even be safe at low doses for self-selection. CBD is freely available in Canada and the United States in a wide variety of dosages. A recent systematic review of clinical evidence by Iffland and Grotenhermen (1) concluded that the safety profile of CBD is high, with minimal events reported in the studies reviewed. Side effects were minor, such as tiredness, diarrhea, and changes of appetite/weight.

As stated, by Iffland and Grotenhermen (1), CBD treatment at lower doses has physiological effects that promote and maintain health, including antioxidative, anti-inflammatory, and neuroprotection effects. As an example, it is suggested that CBD is more effective than vitamin C and E as a neuroprotective antioxidant.

Affected consumers and representative disease groups overwhelmingly supported low cost and easily available consumer access to high-quality CBD products in the recent submissions to the

Senate Inquiry on CBD. The Inquiry recommended that the Therapeutic Goods Administration (TGA) consult with the public on reducing barriers. In particular, Senate Recommendations 12 and 13 provided that the TGA conduct broad public consultation on the down-scheduling of CBD as a matter of priority.

Therefore, we support the down-scheduling of CBD as an essential measure to reduce community barriers to accessing medicinal cannabis in line with the recent Senate Inquiry.

Pharm-a-Care's supported down-scheduling of CBD:

There are two proposals to amend the Scheduled Access to CBD currently under review. We support a **combination** of the TGA & Private applicant proposals currently in front of the Joint ACMS-ACCS Committee, as follows:

1. Pharmacare supports the **Schedule 3 (Pharmacist Only) – New entry** of CBD. However, we have a strong recommendation to allow for **Listing of cannabidiol products (AUST L)** and for cannabidiol to be entered into the Permitted Ingredients Determination as a permitted ingredient for use in Listed (AUST L) or Registered medicines (AUST R). This will allow for greater competition, market access for patients and competitive pricing, but will still support the safe-guard of a health professional intermediary.
2. We support eligibility for Listing with low-level indications to increase availability for patients of high safety, quality and efficacy control. However, we believe the ingredient should be made available for use in Listed medicines through a Minister-led approval of CBD as a Permitted Ingredient that does not disadvantage a competitive marketplace and accessibility to consumers of various high-quality products.
3. We suggest that only whole cannabis plant derived (not synthetic) CBD products should be allowed as it offers the best safety and efficacy to patients, with the recommended cannabinoid content as >98% cannabinoids (cannabidiol as a marker).
4. We support the recommendation that CBD should be for adults over 18 only.
5. We support the 30-day supply pack size.
6. We support the 60mg per day maximum daily dose.
7. We suggest a higher dosage per day be available for compounding-only, which can be based on patient presentation, body weight and mild side effects.
8. We recommend a patient registration requirement is considered in order to monitor patient's compliance to daily dose and reduce the risk of patient accumulating unnecessary products.

9. We suggest that schedule 3 CBD products should be permitted to include other herbs/minerals/vitamins that can safely enhance the overall efficacy of the product for consumer's benefits. For instance, a cannabidiol product with Kava could support mild anxiety or cannabidiol product with Zinc, Vit C could support general wellbeing.

References

1. Iffland K, Grotenhermen F. An update on safety and side effects of cannabidiol: A review of clinical data and relevant animal studies. Cannabis Cannabinoid Res. 2017;2(1):139-154.