AusCann

Secretary
Joint ACMS/ACCS

21 May 2020

Re: Public Notice of 24 April 2020 (item 2.5) for Consultation: Proposed amendments to the Poisons Standard – Cannabidiol

The Company appreciates the opportunity to comment on the scheduling amendments referred to the expert advisory committee contained in the above Public Notice.

AusCann supports changes in the Poisons Standard schedules which will provide patients with better access to quality-controlled, safe and efficacious therapeutic goods. As such AusCann does not support the proposed amendment in its current form.

Our position with regards to the proposed amendment submitted by the Delegate of the Secretary of the Commonwealth Department of Health, is detailed below.

Patient Access Under Schedule 3

AusCann's position is that paramount to any consideration of rescheduling is ensuring Australian patients have access to quality-controlled, safe and efficacious medicines.

The constraint of the proposed entry to a "maximum recommended daily dose of 60mg or less of cannabidiol" and "in packs containing not more than 30 days' supply" constrains the clinical utility of cannabidiol (CBD) which is counter to the intent of making the drug available to the public without a prescription but still with the oversight of a health care provider (the pharmacist).

We note the alignment between the proposed amendment to the scheduling and the TGA review paper *Review on the safety of low dose cannabidiol*[1]. In the background to this review, the TGA indicated that the safety review of CBD at lower doses was directly applicable to the Senate inquiry into *Current barriers to patient access to medicinal cannabis in Australia*[2]. It is therefore not unreasonable to assume that an intention of the rescheduling is to address cannabidiol accessibility as a therapeutic good for Australian patients.

As noted in the aforementioned review by the TGA, the published literature is limited and lacks robustness with regards to the therapeutic value of CBD at these low doses. Proposing a Schedule 3 entry which is constrained to a dose limit where evidence of therapeutic value is lacking, seems counter to the intent of making the quality-controlled, safe and efficacious therapeutic good available for patients.

[1] TGA, Review on Safety of low dose cannabidiol, https://www.tga.gov.au/alert/review-safety-low-dose-cannabidiol, 24 April 2020, Australian Government Department of Health, accessed 15/05/2020
[2] Senate Community Affairs Reference Committee, Current barriers to patient access to medicinal cananbis in Australia, Senate inquiry referred to the Committee on 14 November 2019. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Medicinalcannabis

There is a lack of clarity around the intended pathway for patient access if CBD is rescheduled to a Pharmacist Only Medicine with the included dose constraints, given:

1. CBD is listed on the TGA Ingredient Database as available for use as an active ingredient in export only and prescription medicines;
2. CBD is not permitted to be included in Listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2020;
3. To be available as a Registered medicine, the medicine must be assessed for safety, quality and effectiveness. Given the probable lack of clinical utility at the proposed dose constraint, it is highly unlikely that clinical effectiveness will be evidenced in a clinical program necessary for registration;
4. In the absence of inclusion on the Australian Register of Therapeutic Goods (ARTG) as either an AUST L (not currently permitted, see point 2) or an AUST R (requiring TGA evaluation of safety, quality and efficacy under a full clinical trial program, see point 3), CBD would only be available as an unregistered medicine under special access provisions of the Therapeutic Goods Regulations – equivalent to the current situation.

Considering the points above, AusCann does not see how the proposed changes will result in a registered therapeutic good, providing Australian patients with better access to quality-controlled, safe and efficacious cannabidiol-based medicines.

[redacted]