CANNVALATE

Consultation: Proposed amendments to the Poisons Standard
Regarding Cannabidiol (CBD) re-scheduling to Schedule 3 for low dose oral CBD

Who are Cannvalate

Cannvalate is a medically-led cannabinoid medical clinic and cannabinoid pharmaceutical distribution group. Our clinicians have collectively held over 15,000 patient consultations for prescription-only cannabinoids predominantly via the SAS-B scheme.

Of particular note, is that we have several thousand patients currently on CBD medication supplied as part of a doctor-issued medical prescription. It is for this reason, we are able to comment on the topic of patient safety, utility and suitability for schedule 3 with some authority.

Several thousand patients have been prescribed cannabidiol for a variety of conditions including:

- Chronic pain syndromes (e.g. Chronic Regional Pain Syndrome – CRPS)
- Anxiety and mood-related disorders (e.g. Generalised Anxiety Disorder)
- Chronic inflammatory disorders (e.g. Crohn's Disease, Rheumatoid Arthritis)
- Chronic neurological disorders (e.g. Multiple Sclerosis, Motor Neurone Disease)

About the proposed amendment to the poisons standard

Creating a carve-out for low-dose (under 60mg daily) oral CBD (synthetic or botanical) for inclusion on schedule 3 of the Australian Register of Therapeutic Goods is aligned with our thinking.

We support the TGA's proposal that:

- CANNABIDIOL in preparations for therapeutic use when:
- the cannabidiol is either plant derived, or when synthetic only contains the (-) CBD enantiomer; and
- the maximum recommended daily dose is 60 mg or less of cannabidiol; and
- in packs containing not more than 30 days' supply; and
- cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and
- any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation; and
- for adults aged 18 years and over.

However, we advocate that all products seeking to obtain registration on schedule 3 of the ARTG are required to conduct standard:

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Quality, safety and efficacy studies as per any other pharmaceutical drug to protect patients against the risk of:

- Low quality products which are not manufactured to pharmaceutical grade
- Products containing unacceptable levels of microbes, heavy metals or ash
- Products lacking reproducibility and standardization of active pharmaceutical ingredients (APIs) and excipients
- Therapeutic claims which have not been justified through well-conducted clinical trials

Summary

Cannvalate are a medically-led organisation with a referral network comprising over 2500 Australian registered doctors. We have held over 15,000 clinical consultations with patients advising on and prescribing cannabinoid drugs.

Our senior management are supportive of the down-scheduling of CBD to schedule 3 of the ARTG with the condition that all products being made available OTC still:

- Would have pharmacist-interaction prior to purchase (as per Schedule 3)
- Would have pre-market efficacy assessment for all therapeutic claims
- Would be mandated to meet the quality, safety and efficacy hurdles as per any other pharmaceutical product

Kind Regards,

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Darryl Davies - Chief Operating Officer
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