

14 February 2017

Hon Peter Dunne  
Associate Minister of Health  
Parliament Buildings  
WELLINGTON

Dear Minister

### **Advice from the Expert Advisory Committee on Drugs – Classification for Cannabidiol**

The Expert Advisory Committee on Drugs (the Committee) met on 27 April 2016 and again on 26 October 2016 to consider cannabidiol (CBD) in accordance with section 5AA of the Misuse of Drugs Act 1975 (MoDA).

This letter is to provide you with advice from the Committee regarding CBD on the matters specified in section 5AA of MoDA.

#### **The Committee's Advice**

- Based on the Committee's assessment of CBD's risk profile, lack of psychotropic properties and potential therapeutic value, the Committee would support a decision by the Minister to de-schedule CBD from being captured under MoDA so that it is a prescription medicine only.
- The Committee considers that it would be appropriate for an allowance in CBD preparations of up to 2 percent of other cannabinoids found in cannabis (including  $\Delta^9$ -tetrahydrocannabinol) for therapeutic use only.
- This allowance of 2 percent of other cannabinoids should apply to the proportion of CBD as an active ingredient in a product (ie, the CBD active ingredient must have a minimum of 98 percent CBD and can have up to 2 percent other cannabinoids found in cannabis).

This advice is for CBD only and should not be generalised to any other preparations or substances derived from the cannabis plant. This distinction is important and it must be clear in any communication with the public that removing CBD from MoDA implies no opinion on the "medicinal cannabis" debate and only an opinion on CBD – which does not have psychotropic properties. The Committee notes the risk of confusion to the public on this matter if any relevant communications are not well managed.

The Committee does not have an opinion on what the most appropriate unit of measurement for the restriction of "other cannabinoids found in cannabis" would be

(ie, percentage, milligrams per kilogram or parts per million) but the restriction should not exceed the value of 2 percent.

Differing views were expressed by some Committee members about whether CBD is correctly considered as a controlled drug within the current legislation. The Committee did not reach any conclusion or express any view on that point as it was not necessary to do so in order to provide advice on how CBD should be classified.

The Committee notes Dr Keith Bedford's view that CBD is not currently captured by the 'tetrahydrocannabinols' entry in the MoDA as a B1 controlled drug. The Committee also notes Dr Bedford's disclosure of interest that he has provided an affidavit to that effect in support of potential proceedings, subsequent to the October EACD meeting.

### **Reasoning for the Committee's Advice**

- The likelihood of abuse of CBD is low given that CBD does not have psychotropic properties. For this reason CBD is also unlikely to cause physical or physiological dependence.
- Cannabidiol appears to be well tolerated in studies and so has a low risk of toxicity and is unlikely to cause death.
- There are not expected to be any significant risks to public health with the availability of the substance CBD for therapeutic purposes.
- Cannabidiol research is being conducted into its therapeutic value with clinical trials ongoing.
- This change would align New Zealand's classification of CBD with Australia's new classification.
- Cannabidiol products would continue to be regulated as prescription medicines so appropriate controls around their access, use, safety and efficacy will still be applied.
- The Committee agrees with the following reasoning given for the Australian Advisory Committee on Medicines Scheduling delegate's final decision for the scheduling of CBD (paraphrased for clarity):
  - The schedule entry needs to acknowledge that there is no pure form of CBD currently available. However, the low levels of impurities found in some CBD products are not clinically significant and the scheduling entry should reflect this by allowing other cannabinoids, up to 2 percent.
  - The entry allows for but does not specify any particular non-active cannabis impurity/ies to be within the 'up to 2 percent'.
  - The substances that comprise the 'up to 2 percent' must be substances naturally found in cannabis.
  - The entry does not preclude the CBD and/or any other cannabinoids being derived from natural sources or made artificially as long as they can be found naturally in cannabis.

### **Summary of the Situation**

Currently, with CBD managed as a controlled drug and a prescription medicine and no consented CBD-only products available, CBD products for therapeutic use are only available if approval from the Ministry is given.

If an amendment to MoDA to deschedule CBD were passed, CBD would be available as a prescription medicine. Cannabidiol would no longer be a controlled drug and would not require Ministry approval prior to prescribing.

Yours sincerely

**Expert Advisory Committee on Drugs**