

CLASSIFICATION OF CANNABIDIOL

Discussion Document

1. Introduction

In recent discussions it has become apparent that there is a difference of interpretation between ESR and the Ministry of Health regarding the classification of cannabidiol (CBD) under relevant New Zealand drug legislation. This is of concern to ESR for a number of reasons, including the implications for appropriate charges in criminal prosecutions and the management of requests for access to 'medicinal cannabis' preparations.

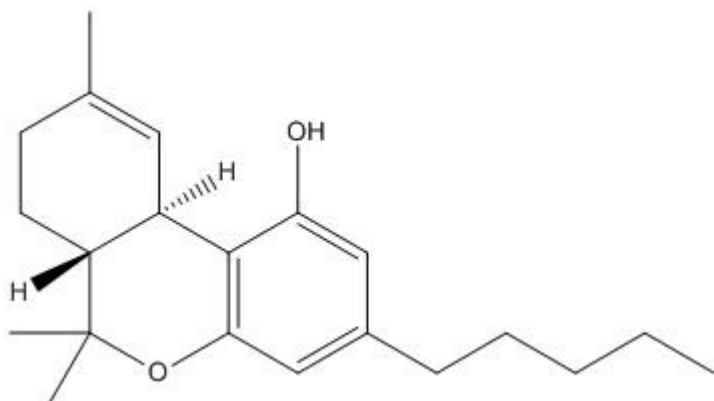
This discussion document seeks to set out ESR's opinion on the chemical designation of CBD, and its subsequent scheduling under the Misuse of Drugs Act 1975 (MoDA) and the Medicines Regulations 1984. In developing the opinion ESR has referenced a document entitled 'Relationship between cannabidiol and THC' provided to ESR by the Ministry of Health (Medicines Control; dated 24 March 2015; attached as appendix 1) which sets out the structural relationship(s) between CBD and THC and presents the Ministry of Health's opinion on the classification of CBD as a Class B controlled drug under the MoDA.

ESR's view on the classification differs from that stated by the Ministry of Health. As outlined in the sections below, ESR does not consider CBD to be a tetrahydrocannabinol, and while it does have the same molecular formula as THC, CBD is not a chemical isomer within the specific chemical designation of THC. As such, CBD cannot be considered as a controlled drug analogue or scheduled as a Class B controlled drug under the MoDA, but rather should be considered a prescription medicine under the Medicine Regulations 1984.

2. CBD as a tetrahydrocannabinol

Of relevance to the discussion is whether CBD can be considered a tetrahydrocannabinol. On Page 1, Paragraph 1, the Medicines Control document accurately states that "*THC could represent any structure with the isolated double bond in the top left ring at one of several positions in the ring*".

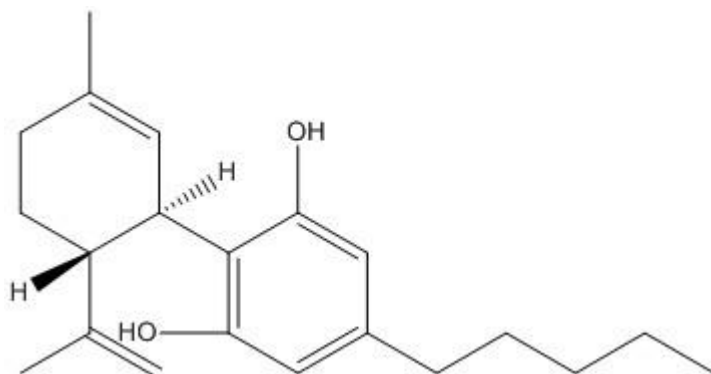
The structure of tetrahydrocannabinol (THC) is presented below:



Tetrahydrocannabinol (THC)

Schedule 2 Part 1, Clause 1 of the MoDA, lists the group of substances “Tetrahydrocannabinols” as Class B controlled drugs.

The structure of CBD is presented below:



Cannabidiol (CBD)

As noted on Page 2, Paragraph 2, the Medicine Control document accurately states “*the lack of an ether link in the pyran unit being a distinguishing feature*” between the chemical structures of THC and CBD. ESR agrees that the lack of this ring structure is significant and therefore excludes classification of CBD as a tetrahydrocannabinol type structure.

3. Relevance of chemical conversion

On Page 2, Paragraph 3, the Medicines Control document states “*that simple acidic mediation could facilitate ring closure of [CBD] to give [THC]*”.

ESR agrees that CBD could be converted to THC under acidic conditions, however this chemical conversion process is not covered by the MoDA. Therefore this process could not be considered a legitimate argument for the Classification of CBD as a Class B controlled drug. The only example of where a chemical conversion process is considered under the MoDA is for the named substance gamma-hydroxybutyrate (GHB), which is listed as a Class B controlled drug in Schedule 2, Part 1 of the MoDA. In Clause 6 (b) of this Schedule, it states “all substances from which GHB can be derived”...“(without limitation)”. This legislation cannot be applied to any other named substances listed in the MoDA.

4. CBD as an isomer of THC

On Page 2, Paragraph 4, the Medicines Control document states “*The first principles definition of an isomer is ‘compounds with the same molecular formula but different chemical structures’.... Therefore, Clause 2 of B1 [MoDA] could adequately capture CBD under the isomer provision and it could be considered in the broad sense as ‘any tetrahydrocannabinol’.*”

Clause 2 of Schedule 2, Part 1, states “The isomers of the substances mentioned in clause 1 whenever the existence of such isomers is possible within the specific chemical designation.”

It is ESR’s opinion that the qualification “...within the specific chemical designation” is critical whilst CBD has the same molecular formula as THC ($C_{21}H_{30}O_2$) it is not an isomer within the specific chemical designation of THC.

5. CBD as a controlled drug analogue

Page 3 of the Medicines Control document goes on to discuss Section 2 of the MoDA, titled “Interpretation”. In this section, Clause 1 defines the definitions of a **controlled drug** and a **controlled drug analogue** as given in the Act. These definitions are as follows:

controlled drug means any substance, preparation, mixture, or article specified or described in Schedule 1, Schedule 2, or Schedule 3; and includes any controlled drug analogue

controlled drug analogue means any substance, such as the substances specified or described in Part 7 of Schedule 3, that has a structure substantially similar to that of any controlled drug; but does not include –

- (a) any substance specified or described in Schedule 1 or Schedule 2 or Parts 1 to 6 of Schedule 3; or
- (b) any pharmacy-only medicine or prescription medicine or restricted medicine within the meaning of the Medicines Act 1981; or
- (c) an approved product within the meaning of the Psychoactive Substances Act 2013

On Page 3, Paragraph 2 of the Medicines Control document, the writer states they “would consider [CBD and THC] substantially similar in the chemical sense” and quotes from the MoDA “*any substance... that has a structure substantially similar to that of any controlled drug*”.

This latter quote is taken from the definition of a controlled drug analogue – the definition of which goes on to specifically state what it **does not include** (i.e. subsections (a), (b) and (c)).

ESR has also considered the analogue definitions of the MoDA when considering the legal classification for CBD.

However, a discussion as to whether CBD is substantially similar to THC, and therefore could be a controlled drug analogue, becomes irrelevant because of subsection (b) of the definition. This effectively states that **any prescription medicine as described by the Medicines Act cannot be considered as a controlled drug analogue**.

Cannabidiol (CBD) is currently listed as a prescription medicine in the Medicines Regulations 1984. (#295 of Part 1 of Schedule 1.)

Also, of note and importance to the conclusions presented in this paper, is that controlled drug analogues are Class C controlled drugs under the Misuse of Drugs Act and as such the consideration of CBD as an analogue of THC would rule out any justification for CBD being a Class B controlled drug.

6. Conclusion in relation to the classification of CBD

Taking the above into consideration ESR concludes the following:

- CBD is not a tetrahydrocannabinol.
- CBD has the same molecular formula as THC, but it is not an isomer within the specific chemical designation of THC.
- CBD cannot be considered as a controlled drug analogue.
- CBD is not controlled under the MoDA.
- CBD is listed as a prescription medicine under the Medicines Regulations 1984.

This difference in opinion poses difficulties for ESR in that when analysing substances containing CBD we would currently state that “CBD is listed as a prescription medicine in the Medicines Regulations 1984”, which we note is in contrast to the Ministry of Health’s interpretation. ESR requests that the Ministry of Health note the detail of this discussion paper, and the conclusions that have been drawn. We would appreciate your feedback and would welcome further discussion about the issue.

ESR