**File number:** AD62-14-2017

**Action required by:** routine

Advice from the Expert Advisory Committee on Drugs on the Classification of Cannabidiol

|  |  |
| --- | --- |
| **To:** | Hon Peter Dunne, Associate Minister of Health |
| **Copy to:** | Hon Dr Jonathan Coleman, Minister of Health |

# Purpose

This paper responds to the Expert Advisory Committee on Drugs’ advice that cannabidiol be descheduled from the Misuse of Drugs Act 1975.

# Key points

* The Expert Advisory Committee on Drugs (the Committee) reviewed the classification of cannabidiol (CBD) at its April and October 2016 meetings.
* CBD is currently classified as a class B1 controlled drug under the Misuse of Drugs Act 1975. CBD is also listed as a prescription medicine in the Medicines Regulations 1984.
* The Committee’s advice is that it would support a decision to deschedule CBD from being a controlled drug. This would make CBD a prescription medicine only (available on prescription).
* The Committee considers it would be appropriate for an allowance of two percent or less of other cannabinoids (including THC) in the CBD component of therapeutic products only. This recognises that naturally-derived CBD products have a high probability of containing other cannabinoids (including THC) as contaminants.
* The Ministry of Health (the Ministry) supports the Committee’s advice, which is attached along with the papers the Committee considered as Appendices 1 and 2.
* Descheduling CBD would not affect the current lack of products. However, it may have an impact on clinicians’ willingness to prescribe and it would streamline the process and reduce the cost to patients of meeting legislative requirements.
* Descheduling CBD would require an amendment to the Misuse of Drugs Act. [redacted under section 9(2)(g)(i)]
* The drafting and passage of an amendment bill would be subject to prioritisation within the government’s legislative programme.
* If an amendment bill to deschedule CBD is not able to be progressed in the near future, some controlled drug requirements for CBD could be removed via amendment to the regulations. This would be an interim measure until CBD can be descheduled and all controlled drug requirements removed.

|  |  |  |
| --- | --- | --- |
| Contacts: | Hannah Cameron, Group Manager, Regulatory Policy Strategy and Policy | 021 783 574 |
| Sharon Woollaston, Senior Policy Analyst, Safety and Access, Regulatory Policy | 496 2028 |

Advice from the Expert Advisory Committee on Drugs on the Classification of Cannabidiol

# Recommendations

**The Ministry recommends that you:**

|  |  |  |
| --- | --- | --- |
| a) | **Note** the Committee’s advice that it would support descheduling CBD as a controlled drug so it is a prescription medicine only. |  |
| b) | **Note** the Committee’s advice that the CBD component of therapeutic products should have an allowable threshold of up to two percent of other cannabinoids (including THC). |  |
| c) | **Note** that the Ministry supports the Committee’s advice. |  |
| d) | **Note** that a Misuse of Drugs Amendment Bill is required to deschedule CBD from the Misuse of Drugs Act and to allow the CBD component of a product to contain up to two percent of other cannabinoids. |  |
| e) | **Indicate** whether you want the Ministry to draft a Cabinet Committee paper seeking approval to:  amend the Misuse of Drugs Act 1975 to deschedule CBD and allow up to two percent of other cannabinoids as contaminants in CBD;  OR  amend the Misuse of Drugs Regulations 1977 to remove some controlled drug requirements for CBD products, as an interim measure until CBD is able to be descheduled via an amendment bill | **Yes / No**  **Yes / No** |
| f) | **Agree** that the Committee’s advice on the classification of CBD (Appendix 1) be published on the Ministry of Health website, at a time to be agreed with your office. | **Yes / No** |

Hannah Cameron **Minister’s signature:**

Group Manager Regulation Policy

**Policy and Strategy Date:**

Advice from the Expert Advisory Committee on Drugs on the Classification of Cannabidiol

**Background**

1. Cannabidiol (CBD) is one of 80 to 100 cannabinoids isolated from the cannabis plant. It has little or no psychotropic properties and no serious adverse events from its use have been reported. Current research indicates that CBD could have therapeutic applications. Public interest in CBD has increased with the emergence of CBD-based products. Most of these products are non-pharmaceutical grade but some pharmaceutical grade product is expected in the future (ie, Epidiolex which is undergoing clinical trials in the United States and Australia).
2. Currently CBD is a class B1 controlled drug under the Misuse of Drugs Act 1975 (MoDA). CBD is also listed as a prescription medicine in the Medicines Regulations 1984 because it can be used for a therapeutic purpose. As a class B1 controlled drug, CBD products can be prescribed and imported but only after Ministry approval has been obtained.
3. Sue Grey (a lawyer who advocates for greater access to cannabis products for therapeutic purposes) and Dr Keith Bedford (formerly of the Institute of Environmental Science and Research Limited) have questioned whether CBD is controlled under MoDA.
4. The Ministry obtained legal advice specifically on this issue. Based on this advice, the Ministry considers CBD is captured by the provision in Schedule 2, Part 1(2) of MoDA as an isomer of tetrahydocannabinol (THC). This means that the Ministry considers CBD is a class B1 controlled drug (see HR 20170058 for further information).
5. A drug captured by MoDA is controlled when present at any level (even at trace level as a contaminant). Naturally-derived CBD products (ie, from the cannabis plant) are very likely to contain small amounts of other cannabinoids, particularly THC. This makes the products controlled drugs regardless of the classification of CBD. The Ministry is not aware of any synthetic CBD products currently available.

**Classification of CBD in Australia**

1. In July 2015 the Therapeutic Goods Administration (TGA) down-scheduled CBD to a prescription only medicine ‘in preparations for therapeutic use containing two percent or less of other cannabinoids found in cannabis’. The two percent allowance of other cannabinoids acknowledges that CBD products are very likely to be contaminated by other cannabinoids, particularly THC. The Ministry’s understanding is Australia allows the CBD component of a product to have up to two percent of other cannabinoids (versus an allowance of two percent of the whole product).

**The Committee’s advice**

1. The Expert Advisory Committee on Drugs (the Committee), provides expert advice to the Minister of Health on drug classification issues. It is the role of the Minister to decide whether to progress recommendations from the Committee.
2. The Committee considered the classification of CBD on 27 April and 26 October 2016. The relevant papers provided to the Committee are attached in Appendix 2. Due to the level of public interest in CBD the Ministry has published the CBD paper provided at the April meeting on the Ministry of Health website. The Ministry intends to publish the documents from the October meeting (Appendix 2), with information that was provided in confidence redacted.
3. The Ministry also proposes publishing the Committee’s advice on the classification of CBD (Appendix 1). With your agreement, this advice will be published on the Ministry website. The minutes from the October 2016 meeting will also be published once you have received the advice on lisdexamfetamine, which the Committee also considered at this meeting.
4. Following its consideration of the classification of CBD, the Committee provided the following advice:

* It would support descheduling CBD from MoDA so that it is a prescription medicine only.
* It would be appropriate for an allowance of up to two percent of other cannabinoids (including THC) in the CBD component of products for therapeutic use.

1. The Committee’s support for an allowance of a two percent threshold of other cannabinoids for therapeutic products acknowledges there are no ‘pure’ CBD products currently available. Even Epidiolex, a pharmaceutical grade product, is 98 percent CBD with up to two percent impurities. If descheduling of CBD products were limited to products that contained CBD only (with no allowance for trace level contamination of other cannabinoids), it is unlikely that any product tested in a laboratory accredited to international standards would meet the criteria to be a prescription medicine.
2. The Committee is concerned that any public communication on this issue is clear that the CBD classification advice is specific to CBD only. The Committee’s CBD advice is not applicable to other formulations of cannabis.

**Response to the Committee’s advice**

1. The Ministry supports the Committee’s advice that CBD be descheduled from MoDA so that it is a prescription medicine only. To improve patient access to CBD products, the Ministry also supports having an allowable threshold of up to two percent of other cannabinoids (including THC) in the CBD component of products.
2. While the Committee’s advice to deschedule CBD is not binding on the Government, a decision to retain the status quo with no amendment to the processes to access and use CBD products would very likely be the focus of broad public criticism.
3. The Ministry is aware that products claiming to be CBD-only are emerging on the market. However, the products are made by companies not accredited to international Good Manufacturing Practice (GMP) standards for pharmaceutical grade products and Certificates of Analysis provided to date have not come from accredited laboratories. The exception is Epidiolex (developed by GW Pharmaceuticals), which is known to be manufactured to GMP and has been tested by an accredited laboratory. Epidiolex is currently undergoing clinical trials. The Ministry is aware of at least one other company looking to gain accreditation in the relevant areas so this situation may change in the future.
4. Descheduling would not affect the current shortage of products produced according to GMP, though it may affect the willingness of clinicians to prescribe CBD products where there is some efficacy data to support its use for a particular patient.
5. Descheduling CBD would streamline the process for patients to access CBD-based products, as products become available. It would also show that the government is looking to remove barriers to access where possible.

**Implementation options**

1. Declassification of CBD as a controlled drug so it is a prescription medicine only would require a Misuse of Drugs Amendment Bill. It is not possible to down-schedule or deschedule a controlled drug by Order in Council. However, it is possible to remove some or most of the additional controlled drug requirements via amendment to the Misuse of Drugs Regulations. This would be an interim measure until CBD were able to be descheduled via a Misuse of Drugs Amendment Bill and all controlled drug requirements removed.
2. There is broad public interest in access and use of cannabis products for therapeutic and recreational use. [redacted under section 9(2)(g)(i)] This would be subject to prioritisation as part of the government’s legislative programme.
3. Anything less than immediate implementation of the Committee’s advice to deschedule CBD is likely to be strongly criticised by cannabis advocates. If amending the Regulations was supported, communications on CBD should be clear that this was an interim measure until CBD is descheduled via an amendment bill.
4. Requirements for CBD products that could be amended via regulation include:

* a requirement for Ministerial Approval to prescribe (delegated to the Ministry)
* a requirement for an import licence to import into New Zealand (approximately $200- per consignment) (prescription medicines can be imported without a licence)
* a restriction to one month period of supply (prescription medicines have a three month period of supply)
* additional requirements around storage and record keeping (as compared to prescription medicines).

1. There are specific restrictions around the cultivation and manufacture of cannabis. Cultivation and manufacture for commercial purposes is not possible while CBD remains a controlled drug. In addition, it is not possible to amend the penalty provisions for CBD via regulation as these are set out in MoDA. The penalties for possession and supply of controlled drugs are significantly higher than for prescription medicines.
2. Amending the Misuse of Drugs Regulations to remove the requirement for Ministerial approval to prescribe CBD is reasonably straightforward. Amendments to licensing, period of supply, storage and recording keeping requirements have the potential to be complex and take longer to design.
3. If amendment to the regulations to remove some or most of the controlled drug provisions for CBD were supported, the Ministry would undertake further analysis on the potential amendments as part of the development of a Cabinet paper seeking agreement to this approach.

**Proposal to allow low-THC hemp seeds in food**

1. While the Committee has been considering the classification of CBD, Food Standards Australia New Zealand (FSANZ) has publicly consulted on whether low-THC hemp seed food should be allowed. Changes to the Misuse of Drugs legislation would be required to permit low-THC hemp seeds in food in New Zealand. The Australia and New Zealand Ministerial Forum on Food has deferred consideration of the proposal until April this year, pending a report on the effect of hemp seeds in food on road side drug testing in Australia.
2. Due to the current controlled drug status of CBD and THC, to permit low-THC hemp seeds in food, changes to the Misuse of Drugs Act legislation would be required. The Ministry of Primary Industries is developing a Cabinet paper seeking approval for the necessary primary legislative changes to be implemented via amendment to the Food Act (this would allow the proposal to be implemented via Misuse of Drugs Regulations).
3. Should the proposal to allow low-THC hemp seeds in food proceed, the Ministry will look for opportunities to progress any legislative amendments for CBD therapeutic products and low-THC hemp seeds in food in tandem.

**END.**