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26 February 2019

[redacted]

Ref: H201900416

Dear [redacted]

Response to your request for official information

I refer to your request of 29 January 2019, under the Official Information Act 1982 (the Act) for:

> *"1. Does NZ allow CBD products (derived from hemp at 1% THC) to be imported from Canada or the US. I note Sativex is produced in the UK and Tilray is based in Canada but also note: "None of the products currently available have consent for distribution in New Zealand. Strict export restrictions on products sourced from some other countries will continue to impact the supply of CBD products in New Zealand." (https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/cbd-products).*
> 2. *What is the process involved in having a CBD product(s) approved/registered by the MOH - Application for New Medicine?*
> 3. *What licences are required to import and "deal" in CBD. I note the following licences, but the terminology "controlled" has me confused.*
> 4. *Licence to deal in a controlled drug*
> 5. *Licence to import a controlled drug - I note "Medical practitioners and pharmacies are allowed to import CBD products, as are persons or companies holding a licence to sell medicines by wholesale" (1/28/2019 Misuse of Drugs (Medicinal Cannabis) Amendment Act | Ministry of Health NZ).*
> 6. *Licence to sell medicines by wholesale*
> 7. *Are there licences or regulations around packaging and transportation that we should be aware of."*

Information held by the Ministry of Health (the Ministry) relating to your request is attached as Appendices One and Two.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review any decision made on this request.

Please note this response (with your personal details removed) may be published on the Ministry's website.

Yours sincerely

Emma Prestidge
Acting Deputy Director-General
Health System Improvement and Innovatio

Appendix One

I have been retained to research the current rules, regulations, supply chains and licences for provision of CBD products in NZ. My NZ client has sourced FDA approved hemp based CBD products through a Canadian company also operating in the US and would like to determine the requirements and pathways for importing and wholesale distribution as a prescription medicine. *Following the Misuse of Drugs (Medicinal Cannabis) Amendment Act, I have found a lot of conflicting information within the online documentation. Given that the Medicinal Cannabis Scheme is still in the development stage, I suspect it will be difficult to obtain online information with any confidence for some time.* *For this reason, I would appreciate any and all information including licences and applications pertaining to the importation and provision of CBD products. Specifically,* *1. Does NZ allow CBD products (derived from hemp at 1% THC) to be imported from Canada or the US. I note Sativex is produced in the UK and Tilray is based in Canada but also note: "None of the products currently available have consent for distribution in New Zealand. Strict export restrictions on products sourced from some other countries will continue to impact the supply of CBD products in New Zealand." (https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/cbd-products).*	Cannabidiol (CBD) containing products are able to be imported into New Zealand. However, the specific contents of the product will determine any licensing requirements. CBD is scheduled as a prescription medicine in the Medicines Act 1981. CBD products may also contain other constituents, for example tetrahydrocannabinol (THC), which is a controlled drug. Section 2A of the Misuse of Drugs Act 1975 defines a CBD Product (refer Appendix Two), and CBD Products are not classified as controlled drugs. The holder of an appropriate authorisation (for example, a Licence to Sell Medicines by Wholesale that authorises the wholesaling of CBD products) does not require a Licence to Import Controlled Drugs when importing CBD products. Particular care is required when determining if a product is a CBD product. Further information on CBD products is available on the Ministry website at www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/prescribing-medicinal-cannabis-products. Please note that Sativex (which has consent for distribution in New Zealand) and some of the Tilray products do not meet the definition of a CBD Product, and are classified as 'Class B1 controlled drugs'. Importation of these by the holder of an appropriate authorisation (for example a Licence to Deal in Controlled Drugs) requires a 'Licence to Import Controlled Drugs' The Ministry is unable to provide regulatory guidance on legislation in overseas jurisdictions that may determine if a specific product could be exported from that country. The relevant regulatory authority in the country the export is intended to come from should be contacted to determine their current requirements.

Appendix One

2. What is the process involved in having a CBD product(s) approved/registered by the MOH - Application for New Medicine?	Information on the medicine approval process is available on Medsafe's website: www.medsafe.govt.nz/Medicines/regulatory-approval-process.asp.
3. What licences are required to import and "deal" in CBD. I note the following licences, but the terminology "controlled" has me confused. *4. Licence to deal in a controlled drug* *5. Licence to import a controlled drug - I note "Medical practitioners and pharmacies are allowed to import CBD products, as are persons or companies holding a licence to sell medicines by wholesale" (1/28/2019 Misuse of Drugs (Medicinal Cannabis) Amendment Act | Ministry of Health NZ).* *6. Licence to sell medicines by wholesale*	Please refer to response to Question 1
7. Are there licences or regulations around packaging and transportation that we should be aware of.	In respect of wholesale distribution of CBD Products, the holder of a licence to sell medicines by wholesale is required to comply with parts 4 and 5 of the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods. This includes reference to transport, and is publically available on the Medsafe website at www.medsafe.govt.nz/regulatory/Guideline/code.asp.
To reiterate, I understand the Medical Cannabis Scheme is in its infancy and that licencing regimes, introduction of standards and establishment of an agency are in development. *Nevertheless, I would appreciate any information you can provide regarding current requirements and how this might change in the future.*	Information relating to the Medicinal Cannabis Scheme, including stakeholder engagement, is available on the Ministry website: www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/medicinal-cannabis-scheme.

Appendix Two

Misuse of Drugs Act 1975: Section 2A Meaning of CBD product

(1) **CBD product** means a product that—

(a) contains cannabidiol; and

(b) either—

(i) does not contain a specified substance; or

(ii) contains specified substances in an amount that is no more than 2% of the sum of the amount of cannabidiol and the amount of specified substances in the product; and

(c) does not contain any other controlled drug; and

(d) does not contain any other psychoactive substance (as defined in section 9 of the Psychoactive Substances Act 2013).

(2) In this section, **specified substance** means a substance that—

(a) naturally occurs in cannabis; and

(b) is—

(i) a tetrahydrocannabinol; or

(ii) an isomer, ester, or ether of a tetrahydrocannabinol; or

(iii) an ester or ether of an isomer of a tetrahydrocannabinol; or

(iv) a salt of any substance described in subparagraphs (i) to (iii); or

(v) a substance that has a structure substantially similar to that of any substance described in subparagraphs (i) to (iv); and

(c) for substances listed in paragraph (b)(ii) to (v), is capable of inducing more than a minor psychoactive effect, by any means, in a person