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21 June 2022

#### s 9(2)(a)

By email: <u>s 9(2)(a)</u>

Ref: H202206795

Dear s 9(2)(a)

#### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 23 May 2022. Your request has been broken down into two parts and responded to below:

Please could you supply me with data on medicines containing cannabidiol (CBD) and/or tetrahydrocannabinol (THC) supplied under Section 29 during the period April 2018 to June 2022. In order to protect commercial sensitivities, I am specifically seeking pack numbers broken down by the following:

Oil products

CBD 100mg/ml dose - with 25 or 30ml pack size

CBD 100mg/ml - with 40ml pack size

CBD 25 mg/ml or less – all pack sizes

THC/CBD combination (balanced) - all pack sizes

THC alone – all pack sizes

Flower products

THC dominant (<1% CBD)

Balanced

CBD dominant (<1% THC)

I would like the number of packs supplied for each month during the time period, as per the data collected by the Medsafe Declaration Notification Form for medicines supplied pursuant to Section 29 of the Medicines Act 1981.

The information provided in Appendix 1 attached to this response relates to the number of packs supplied each month under the exemption provisions in section 29 of the Medicines Act 1981.

When considering these data, it is important to note:

- That the number of packs supplied cannot be used to determine the number of prescriptions or the number of patients.
- Reporting information is supplied retrospectively and therefore the number of packs reported as supplied in this response is accurate at the time of preparing the response but may change if additional reports are received.
- Sativex has consent for distribution as a medicine, and so supply of Sativex is not included in the figures supplied. Information on the supply of Sativex is not held by either the Ministry or Medsafe.

Table 1: Please note that the information provided relates to products that meet the definition of a CBD product in section 2A of the Misuse of Drugs Act 1975, where any other specified

substances present must not be present in quantities greater than 2% of the amount of CBD in the product.

Table 2 contains information on the number of packs of products that contain only THC.

Table 3 contains information on the number of packs of products containing both CBD and THC. Please note that this includes all products that contain a combination of both CBD and THC.

Information regarding the number of packs supplied, broken down as requested, is withheld under the following sections of the Act:

- section 9(2)(ba)(i) of the Act, to protect information which is subject to an obligation of
  confidence or which any person has been or could be compelled to provide under the
  authority of any enactment, where the making available of the information would be likely
  to prejudice the supply of similar information, or information from the same source, and it
  is in the public interest that such information should continue to be supplied; and
- section (9)(2)(b)(ii) of the Act as releasing this information would be likely to unreasonably prejudice the commercial position of the person who supplied or who is the subject of the information.

I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Could we please have, for each product that has met the Minimum Quality Standards for Medicinal Cannabis Products in New Zealand that are approved for prescription in NZ.

We would like:

- A. The list of excipients used
- B. The active ingredient and dose
- C. The names and addresses of all manufacturers of the active ingredients and excipients
- D. The names and addresses of companies responsible for:
- a. Finished product testing
- b. Packing
- c. NZ site of product release
- E. Certificate of Analyses for each product

Sativex is the only medicinal cannabis with consent for supply as a medicine. Some of the information you are requesting is available by searching on the Medsafe website at <a href="https://www.medsafe.govt.nz/regulatory/DbSearch.asp">www.medsafe.govt.nz/regulatory/DbSearch.asp</a>. The additional information requested is withheld under sections 9(2)(ba)(i) and 9(2)(ba)(ii) of the Act or under section 18(g)(i) of the Act as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act (in regards to the names and addresses of all manufacturers of excipients).

Other medicinal cannabis products that have been verified as meeting the minimum quality standard for medicinal cannabis products are supplied as unapproved medicines under the exemption provisions in Section 29 of the Medicines Act 1981. Such supply includes reporting requirements. Some of the information you are requesting about these products is published on the Ministry of Health website at <a href="https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-health-professionals/medicinal-cannabis-products-meet-minimum-quality-standard">https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-health-professionals/medicinal-cannabis-products-meet-minimum-quality-standard</a> The additional information requested is withheld under sections 9(2)(ba)(i) and 9(2)(ba)(ii) of the Act or is refused under section 18(g)(i) where the information is not held by Medsafe or the Ministry.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: <a href="mailto:info@ombudsman.parliament.nz">info@ombudsman.parliament.nz</a> or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: <a href="www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests">www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</a>.

Yours sincerely

Chris James

**Group Manager** 

Medsafe

# Appendix One: List of documents for release

#	Date	Title	Decision on release
1	2018 - 2022	Tables containing pack information	Released with some information withheld under the following sections of the Act:  • Section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and  • Section 9(2)(ba)(i) to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source.

# **APPENDIX 1**

Table 1 - Number of packs of products that contain cannabidiol and that meet the definition of a CBD product

#### 2018

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug (	Sept	Oct	Nov	Dec
No. of	15	46	74	122	160	247	171	160	241	355	184	315
packs	43	40	'4	122	100	241	171	100	241	333	104	313

# 2019

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of packs	266	177	280	360	532	299	619	464	1328	573	1208	887

#### 2020

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	1002	1355	1644	1175	1325	1914	1982	1870	2436	1621	2874	2766
packs	1002	1333	1044	1175	1323	1914	1902	1070	2430	1021	2074	2700

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	1891	2445	2774	1972	2656	2403	2537	2036	2055	1468	2362	2446
packs	1091	2443	2//4	1912	2030	2403	2551	2030	2055	1400	2302	2440

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Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	2140	2315	2618	2380					. ()			
packs	2140	2313	2010	2360								

# Table 2 - Number of Packs of products containing tetrahydrocannabinol

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Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of							7,0					
packs	_	_	_	-	-	_	7	-	-	-	-	-

# 

Month	Jan	Feb	Mar	Apr	May Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of						2	2	1	1	1	16
packs	-	-	-	-		3		4	4	4	10

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Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	0		0		10	25	10		24	24	47	52
packs	9	-	9		10	25	10	-	24	34	47	55

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	26	181	68	158		280	189	268	460	297	334	350
packs	20	101	00	130	-	200	109	200	400	291	334	330



Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	404	325	373	372					7			
packs	707	020	373	312				. (				1

# Table 3 - Number of Packs of products containing both tetrahydrocannabinol and cannabidiol

# 2018

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	7	16	10	12	16	21	17	10	17	20	21	24
packs	<b>'</b>	10	18	13	10	21	<b>&gt; 17</b>	19	17	20	۷1	24

# 2019

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	22	25	1.1	28	38	39	15	10	57	22	60	24
packs	22	25	14	20	30	39	15	10	57	33	00	24

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	33	54	63	101	74	110	117	110	164	234	230	315
packs	33	54	03	101	74	110	117	110	104	234	230	313

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Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	136	213	132	550	548	668	665	768	632	569	726	1013
packs												

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of	790	580	1075	1177				5/4				
packs												