MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

5 August 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022007093

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 Manatū Hauora (the Ministry of Health) on 9 July 2022 for:

> *With respect to OIA request H202206795, thank you for the information that you have provided. It is useful however I would like some clarification please.*
>
> *Is the number of pack information that you have provided, oils only? If it is not oils only and does include flower products, are you able to break out the number of flower products? If it oils only and does not include flower products, are you able to provide the number of packs of flower products?*

The information on the number of packs relates to all products containing either CBD, CBD/THC, or THC, as per the information provided with the tables in the response to OIA H202206795. It does not differentiate between presentations, dose forms or strengths. The additional information requested is withheld under section 9(2)(b)(ii) of the Act, as it would likely unreasonably prejudice the commercial position of the person/persons who supplied 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.

> *Also, I have asked for some further information on the medicinal cannabis products and you have sought to withhold the information on the basis of Section 9(2)(ba)(i) and (ii) of the OIAct. We reject this rationale for refusal as all other medicines approved in NZ are made public through your own database online. Fundamentally, my question is why are medicinal cannabis products treated differently from other NZ medicines? All other NZ medicinal products have this detailed information as per your database - https://www.medsafe.govt.nz/regulatory/DbSearch.asp Why not medicinal cannabis products? We know the information is available, as the Ministry has the data broken down as requested as it is contained on the notification forms seeking product approval. There is no commercial justification that overrides the public interest in detailed information on the use of medicines which are unregistered due to their unproven safety and efficacy, AND for which there is a potential for abuse (due to their containing controlled substances and are in formats typically used in recreational settings). The Pharmaceutical Data Web Tool allows any person to view the quantum of all medicines dispensed in the community and funded by the New Zealand Government during the time period 2016-2022. Data on the number of scripts dispensed as either initial or continuing scripts can be searched and filtered by year of dispensing, medicine (at chemical formulation, chemical, therapeutic group level 2 and*

therapeutic group level 3) and district health board, as well as pharmaceutical form (e.g. Tab 300mg, Cap 10mg etc) . In fact, the entire data set for 2016-2022 can be downloaded in CSV format and extensively analysed.

In addition, we reject the argument that providing the information would "likely to prejudice the supply of similar information, or information from the same source". The information requested is supplied on Medsafe's Section 29 Declaration/Notification Form, the fulfilment of which is a legal requirement of the supplier under Section 29 (2) of the Medicines Act 1981. A supplier cannot elect unilaterally whether it wishes to comply with the law simply because it does not like what the government subsequently does with that information.

Section 20 of the Medicines Act 1981 requires that before any medicine can be advertised, supplied, distributed or sold in New Zealand, consent must first be obtained from the Minister of Health or their delegate. There are some exceptions to this requirement, one of which is supply by a medical doctor of an unconsented/unapproved medicine to a patient under his/her care (section 29 of the Medicines Act 1981).

Sativex is the only medicinal cannabis product that has consent for distribution as a medicine. Information about this medicine is published on the Medsafe website through the product search function.

Information about medicines supplied under the exemption provisions in section 29 (essentially unapproved medicines) is not publicly available as these medicines have not been approved as medicines by Medsafe. The data you refer to that is searchable on the Medsafe website is only available for approved medicines and medicines that are pending approval.

Information about products verified under the Medicinal Cannabis scheme is available on the Ministry of Health website at: 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.

Also note that as the products you refer to are not funded by Pharmac, data on their supply volumes is not publicly available.

Medsafe stands by its decision to withhold information under sections 9(2)(ba)(i) and 9(2)(ba)(ii) of the Act. If you believe that the response you have received is incorrect, or that the Ministry has withheld information without justification, you have the right to ask the Ombudsman to review any decisions made under your request under section 28(3) of the Act. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Yours sincerely

Chris James
Group Manager
Medsafe