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3 July 2024

M Woodward

By email: fyi-request-26497-6235d018@requests.fyi.org.nz
Ref: H2024044075

Tēnā koe M Woodward

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 – Manatū Hauora (the Ministry) on 10 June 2024 for information regarding medicinal cannabis. Please find a response to each part of your request below.

> "*Regarding: "Total amount of medical cannabis products recalled including product details, why they were recalled and how many patients were affected. " Are you able to provide how many patients were affected as this is not available in the links provided?*

The information you have requested is withheld in full under section 9 (2)(b)(ii) of the Act, as releasing this information would likely unreasonably prejudice the commercial position of the person 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.

> *Regarding: "Any information about how effective the recall was, including how many patients returned their product " I don't believe that this should be refused entirely under section 9 (2)(b)(ii) of the Act. Please consider releasing the size of the batches recalled, specifically Kikuya Arroyo, and how much of this batch was dispensed.*

The process for managing a medicine (or medical device) recall is described in the New Zealand Medicines and Medical Devices Recall Code published on the Medsafe website at: www.medsafe.govt.nz/safety/recall-code-2015.asp. Please see section 6 in the Recall code which describes the process that sponsors (suppliers) are to follow.

Documents discussing the particular steps taken by the company are withheld under the following sections of the Act:

- Section 9(2)(b)(ii); and
- Section 9(2)(ba)(i), as their release would also 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.

> *If specifics can't be provided, please apply these questions to the medical cannabis scheme as a whole and not broken down into product type (ie Total amount of medical cannabis*

units recalled & Any information about how effective the recall was, including total amount of units returned, since April 1 2020)"

The recall process for medicinal cannabis is the same as the recall process for any medicine. It is described in the Recalls Code linked above.

Companies provide information to Medsafe on the progress of the recall, the identification of root cause, and any corrective actions to be taken as a consequence. Medsafe reviews the information supplied and only closes the recall when all issues have been addressed. Specific details in relation to each recall are withheld under the following sections of the Act:

- Section 9(2)(b)(ii); and
- Section 9(2)(ba)(i).

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe