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

10 December 2020

[redacted]

By email: [redacted]
Ref: H202008432

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 23 November 2020 for information about:

> *"… what products are in the pipeline for approval for medicinal cannabis? I see from the Ministry of Health website that applications opened on April 1st of this year for products to be accessed.*
>
> *I am wondering how many products are currently undergoing assessment and an ETA for any of products to be approved? …"*

To clarify, medicinal cannabis products are not approved under the Medicines Act. Information in response to your request is answered below regarding applications received by the Medicinal Cannabis Agency (the Agency) for verification of products against the medicinal cannabis minimum quality standard under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. A new medicinal cannabis product application is formally accepted for assessment once the application has passed an initial check of completeness and the Agency has received payment of the product assessment fee.

To the date of your request, 23 November 2020, nine applications for medicinal cannabis products have been formally accepted for assessment against the minimum quality standard and are currently under assessment. The products are tabulated in Table One overleaf, for your information.

Table One: Medicinal Cannabis products under assessment

Proposed product name	Type of product
Tilray THC 1: CBD 25	Dosage product
Tilray FS Oral Solution THC 25	Dosage product
Tilray FS Oral Solution THC 2: CBD 100	Dosage product
Tilray P Oral solution CBD 25	Dosage product
Tilray P Oral Solutions CBD 100	Dosage product
Tilray FS Oral Solution THC 10: CBD 10	Dosage product
Tilray THC 5: CBD 20	Dosage product
ANTG Eve	Dried product
aZana THC10 CBD15	Dosage product

Also, to the date of your request, a further six applications for medicinal cannabis products have been received that are undergoing an initial check of completeness before a decision is to be made as to whether they can be formally accepted for assessment.

A list of the applications that have been formally accepted for assessment against the minimum quality standards will be published soon on the Medicinal Cannabis Agency page of the Ministry of Health website at: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency.

At present, the Agency is unable to provide an estimate of when any product or ingredient will be verified as complying with the minimum quality standard. There are many factors which will influence this time frame, including the quality of the information provided in the application, the ability of the applicant to demonstrate that they meet the requirements of the legislation, and the time taken for the applicant to respond to the Agency's request for further information. Once products are verified as complying with the quality standard, they will also be listed on the Ministry of Health website (please see above link).

I trust this information fulfils your request. 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 Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe