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B Haddock

By email: fyi-request-14043-c3048390@requests.fyi.org.nz
Ref: H202007996

Dear B Haddock

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 27 October 2020 for:

> *"I understand that various medicinal cannabis products are currently undergoing reviews to become approved medicines. This includes MediPharm Labs products, which Helius Therapeutics Ltd and Cannasouth Ltd have entered in to supply agreements for.*
> *Can you please supply a list of products that:*
> *1. Have been considered for approval as approved medicines, with a final outcome decided.*
> *2. Were not considered for approval as approved medicines, as they did not meet basic or qualifying criteria.*
> *3. Are currently under consideration for approval as approved medicines."*

Firstly, for clarification, assessment of medicinal cannabis products by the Medicinal Cannabis Agency (the Agency) for verification against the minimum quality standard is completely different from consent for distribution or 'approval' of medicines under the Medicines Act 1981.

Approved medicines have been assessed by Medsafe for safety and efficacy for their approved indications, in addition to assessment of their quality. Sativex™ is currently the only medicinal cannabis product that is an 'approved medicine' under the Medicines Act 1981

Under the New Zealand Medicinal Cannabis Scheme, medicinal cannabis products and ingredients must be verified by the Agency as meeting the minimum quality standard which is set in Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019, and licensed for supply. Medicinal cannabis products that are verified by the Agency as complying with the minimum quality standard are not approved medicines under the Medicines Act 1981 but remain unapproved medicines.

Medicinal cannabis products that are approved (such as Sativex™) or provisionally approved under the Medicines Act 1981 are not required to meet the minimum quality standard as they will have already been assessed and approved.

Information in response to each part of your request is provided below regarding applications received by the Agency for assessment and verification of medicinal cannabis products and ingredients against the minimum quality standard, rather than approval as medicines under the Medicines Act 1981. A new medicinal cannabis product application is considered to be formally

accepted for assessment once the application has passed an initial check for completeness and the Agency has received payment of the product assessment fee.

"1. Have been considered for approval as approved medicines, with a final outcome decided."

To date, no medicinal cannabis product applications formally accepted for assessment by the Medicinal Cannabis Agency have reached the point where a recommendation can be made to the Director-General of Health, to be verified as complying with the minimum quality standard.

"2. Were not considered for approval as approved medicines, as they did not meet basic or qualifying criteria."

To date, five applications for assessment of medicinal cannabis products have been received by the Medicinal Cannabis Agency that have not been formally accepted for assessment against the minimum quality standard as they did not pass an initial check for completeness.

"3. Are currently under consideration for approval as approved medicines."

To date, nine applications for medicinal cannabis products and ingredients have been formally accepted for assessment against the minimum quality standards and are currently under assessment. The products are tabulated in Table One below, for your information.

Table One: Medicinal Cannabis products currently under assessment

Proposed product name	**Type of product**
Tilray FS Oral Solution 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 FS Oral Solution THC 5: CBD 20	Dosage product
Tilray CBD crystal	Cannabis-based ingredient
ANTG Eve	Dried product

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

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 as the applications are currently under assessment. Under normal circumstances, we would expect an application could take up to 60 working days from acceptance of the application for assessment through to verification against the minimum quality standard. This includes time for the Agency to assess the application and to request further information or analytical results, and assess any further information provided. However, 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.

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