MEDICINAL CANNABIS AGENCY

MINISTRY OF HEALTH
MANATŪ HAUORA

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6 October 2020

[redacted]

By email: [redacted]
Ref: H202007018

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 7 September 2020 for:

> *"- How many applications for medicinal cannabis product assessments have been made to the Medicinal Cannabis Agency*
> *- The dates these applications were made*
> *- Any Medicinal Cannabis Agency policies on the timeframe for assessing medicinal product applications."*

Under the New Zealand Medicinal Cannabis Scheme, medicinal cannabis products and ingredients must be verified by the Medicinal Cannabis Agency (the Agency) as meeting the minimum quality standard which is set in Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. A product is not required to meet the minimum quality standard if it has received consent (such as Sativex) or provisional consent as a medicine by the Minister of Health under the Medicines Act 1981.

As at 7 September 2020, the Agency had received 12 applications for the assessment of a new medicinal cannabis product or ingredient under the Medicinal Cannabis Scheme. The dates these applications were made are set out in the table below, along with the type of product.

Type of product	**Date received**
Dosage product	28/06/2020
Dosage product	29/06/2020
Dosage product	29/06/2020
Dosage product	29/06/2020
Dosage product	29/06/2020
Dosage product	29/06/2020
Dosage product	29/06/2020
Dosage product	29/06/2020
Cannabis-based ingredient	08/07/2020
Cannabis-based ingredient	03/08/2020
Cannabis-based ingredient	19/08/2020
Dried product	07/09/2020

At present, the Agency is unable to provide an estimate of when any product 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 the further information provided. 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 to respond to the Agency's request for further information.

A new medicinal cannabis product application is considered to be accepted for assessment once the application has passed a completeness check and the Agency has received payment of the product assessment fee.

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.

Please note that this response, with your personal details removed, may be published on Medsafe's website.

Yours sincerely

Chris James
Licensing Authority
Medicinal Cannabis Agency