

4 September 2020

By email: [REDACTED]
Ref: H202006002

Dear [REDACTED]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 11 August 2020.

Information answering your questions can be found below. These are responded to under the titles of 1, 2 and 3 as you have used in your request.

1. Please advise what prescription cannabis products have been submitted to the Medicinal Cannabis Scheme.

The Medicinal Cannabis Agency (the Agency) has received applications for eight dosage products:

- Blessed CBD Oil 750 mg
- Tilray FS Oral Solution THC 1 :CBD 25
- Tilray FS Oral Solution THC 10 :CBD 10
- Tilray FS Oral Solution THC 2 :CBD 100
- Tilray FS Oral Solution THC 5 :CBD 20
- Tilray P Oral Solution CBD 100
- Tilray P Oral Solution CBD 25

2. When can doctors expect to be able to prescribe them?

Doctors can currently prescribe any medicinal cannabis product that does not meet the minimum quality standard as per the regulations stated below.

Regulation 6(2)(c) and (d) of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019:

However, a cannabis-based ingredient or medicinal cannabis product need not comply with the minimum quality standard if—

(c) it is prescribed, supplied, or administered—

(i) by a medical practitioner for the treatment of a particular patient currently under their care; and

(ii) with the approval of the Minister under regulation 22 of the Misuse of Drugs Regulations 1977; or

(d) it is imported by a pharmacist for a prescription to which paragraph (c) applies.

Regulation 4A(2)(a) and (b) of the Medicines Regulations 1984:

(2) However, the minimum quality standard does not apply to a CBD product that is imported by—

(a) a medical practitioner whose purpose is to prescribe, supply, or administer it for the treatment of a particular patient under their care; or

(b) a pharmacist for a prescription to which paragraph (a) applies.

Once a product has been verified by the Agency as complying with the minimum quality standard, it is able to be prescribed (or supplied or administered) without meeting the conditions of the regulations stated above.

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, 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 timeframe, 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.

3. Has MoH received applications for dried flower prescription cannabis?

The Agency has not received any applications for the assessment of a medicinal cannabis product that is a dried product (dried cannabis flower).

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 the Ministry website.

Yours sincerely



Chris James
Licensing Authority
Medicinal Cannabis Agency