MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth St
PO Box 5013
Wellington 6145
New Zealand
T+64 4 496 2000

26 OCT 2018

[redacted]

Ref: H201807005

Dear [redacted]

Response to your request for official information

I refer to your email of 16 October 2018, requesting under the Official Information Act 1982 (the Act):

> *"Interested in understanding the regulations and timeline for the go-live date of medicinal Cannabis in New Zealand.*
>
> *This link below mentions a Health Ministry Document, released under the Official Information Act to National's associate health spokesman Shane Reti. I am interested in reading that document*
>
> *Link - https://www.newstalkzb.co.nz/on-air/mike-hosking-breakfast/audio/paul-manning-health-ministry-criticised-for-mid-2020-date-to-legalise-medicinal-cannabis/".*

The commencement date for the Misuse of Drugs (Medical Cannabis) Amendment Bill (the Bill) is still under active consideration. Therefore, I refuse your request pursuant to section 18(e) of the Act as the information requested does not exist.

It is unclear what document is being referred to in the news article, however, attached as Appendix One is a recent update on the Bill. Some information is withheld pursuant to section 9(2)(a) of the Act to protect the privacy of natural persons.

You have the right, under section 28 of the Official Information Act 1982, to ask the Ombudsman to review my decision on your request.

Yours sincerely

Todd Krieble
Acting Deputy Director-General
System Strategy and Policy

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Memorandum: Medicinal Cannabis update

To: Hon Julie Anne Genter, Associate Minister of Health

Copy to: Hon Dr David Clark, Minister of Health

Purpose

1. This memorandum provides an update on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill (the Bill) and the Medicinal Cannabis Scheme.

Misuse of Drugs (Medicinal Cannabis) Amendment Bill

2. The Bill was introduced in December 2017, had its first reading in January 2018, and is currently being considered by the Health Committee. The Health Committee is expected to report back the end of July 2018.

3. The Bill:
   - provides an exception to the offence, and a defence to the charge of possessing and using illicit cannabis for people who have a terminal illness
   - allows Government to make regulations to set quality standards for medicinal cannabis products, and
   - removes cannabidiol (CBD) from the Misuse of Drugs Act, so that it is no longer a controlled drug.

4. The Bill is a key component in establishing a Medicinal Cannabis Scheme (the Scheme). The Scheme aims to provide a greater supply of quality medicinal cannabis products by enabling domestic cultivation and manufacture (further detail on the Scheme is provided later in the memo).

Exception and defence

5. The Scheme will take time to develop and implement, and we know that some people with a terminal illness are currently using illicit cannabis (that is cannabis that is for recreational use or self-medication, and is not prescribed).

6. The Bill therefore provides an exception for people who have a terminal illness, and who hold evidence from their doctor of that illness. This means they will not be committing an offence in possessing or using cannabis, or possessing a cannabis utensil. If they can produce evidence at the time of questioning, they will not be prosecuted by the Police.

7. The Bill also provides a defence to a charge of using and possessing cannabis, or a cannabis utensil, for people who have been diagnosed with a terminal illness. If they do not have a doctor's certificate at the time of questioning, but can produce evidence of their terminal illness in Court, they will have a defence against conviction.

8. The effect of these provisions will be that the terminally ill will be able to use cannabis without the fear of criminal conviction. These provisions will apply to people of any age who are reasonably expected to pass away within 12 months. This is a compassionate approach for this particular group

Contacts:	John Doyle, Acting Group Manager, Strategy and Policy	s 9(2)(a)
	Helen Fielding, Senior Policy Analyst, Strategy and Policy	04 816 3695

of people, where the usual concerns around product safety, quality, efficacy, and long-term risks are different.

Quality Standards

9. The Bill introduces a regulation-making power that allows quality standards to be set for products supplied under the Scheme. Without the provision in the Bill, there is no ability for the Scheme to require that products meet a quality standard.

10. Quality standards will provide practitioners with assurance that products supplied under the Scheme have known composition and limited contaminants (such as pesticides and heavy metals). The standards are likely to cover the manufacturing process, and the quality of the end product. The standards will apply to all products, both produced domestically and imported.

11. The setting of quality standards will be led by the Ministry of Health, as part of the establishment of the Scheme. This work will be informed by the approach taken in other jurisdictions, expert technical advice, and stakeholders.

Descheduling CBD

12. The Bill will deschedule CBD so it is no longer a controlled drug, in response to the advice of the Expert Advisory Committee on Drugs (the Committee who provides expert advice to the Minister of Health on drug classification issues).

13. The Committee advised that CBD has potential therapeutic value and little or no psychoactive properties, and it would support descheduling CBD as a controlled drug. Naturally-derived CBD products from the cannabis plant are very likely to contain small amounts of other cannabinoids, including tetrahydrocannabinol (THC) which at such low levels is unlikely to have a psychoactive effect. The Committee considered an allowance of two percent of other cannabinoids found in cannabis would be appropriate for CBD products. This two percent allowance aligns with the Australian scheduling of CBD.

14. The Regulations were amended last year to remove a number of controlled drug restrictions for the import and prescribing of CBD products. However, it was not possible to remove all controlled drug restrictions for CBD by Regulations. The Amendment Bill will declassify CBD and CBD products, with less than two percent of other cannabinoids.

Medicinal Cannabis Scheme

15. A Scheme is being established to provide a supply of quality medicinal cannabis products. It will:

    - *make more quality product available* – enabling domestic cultivation and manufacture could allow a supply of quality medicinal cannabis that is readily available.

    - *be easier to identify quality products* – provision will be made to allow the agency to inform prescribers of products that meet the quality standards. Doctors will be able to prescribe these products with confidence. They will be assured that the composition of a product is accurate, and any contaminants minimised.

    - *ensure faster access* – as quality cannabis products will be available in New Zealand, doctors will no longer have to spend time researching potential products, verifying product quality, and arranging import licenses. Patients will be able to access these products faster.

16. The Scheme will cover all cannabis products used therapeutically. A doctor's prescription will continue to be required for anyone to access medicinal cannabis. The Ministry of Health will provide guidance to health practitioners about identifying products that meet the required quality standards and on the prescribing process. The scheme will not enable grow-your-own cannabis.

17. Three key things need to happen to establish the Scheme:
    - the Amendment Bill needs to be in force to provide the mechanism to require products meet quality standards
    - quality standards and the corresponding regulations need to be developed, and
    - an Agency needs to be established to oversee the licensing system.
18. The scheme will be established in 2020.

Framework of the Scheme

19. The Scheme will require that products supplied in New Zealand, including those imported and produced domestically, meet the quality standards set by the Regulations. Manufacturers and importers will have to show that the composition is true to label, and products are free from contaminants.

20. A government agency will be established to oversee the licensing system for cultivation and manufacture of cannabis produced domestically. This is to comply with our international obligations under the United Nations Single Convention on Narcotic Drugs 1961 which requires a government agency to license cultivation of medicinal cannabis. All other stages of the process of producing medicinal cannabis products will also require a licence, including processing, manufacture, import, export, and distribution.

END.