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14 June 2021

Tadhg Stopford

By email: tadhg@thehempfoundation.org.nz
Ref: H202106211

Dear Tadhg Stopford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 19 May 2021 for information regarding medical cannabis. You specifically requested:

> *"… information that was provided to minister Little regarding 'medical' cannabis. Ie. what it is, how it works, it's safety and efficacy, physiological basis, and commercial relevance"*

Four documents have been identified within the scope of your request. These documents are itemised in Appendix 1 to this letter, and copies of the documents are enclosed.

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

Caroline Flora
Group Manager, Family and Community Health Policy
System Strategy and Policy

Appendix 1: List of documents for release

#	Date	Title	Comments
1	12 February 2021	Briefing HR20210334: Medicinal Cannabis Scheme Transition Period	Released with some information withheld under section 9(2)(a) of the Act to protect the privacy of natural persons.
2	3 March 2021	Briefing HR20210451: Cabinet paper to further extend the transitional period for the medicinal cannabis scheme	
3	N/A	Cabinet Lodgement: Amending the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 to further extend the transitional period for the Medicinal Cannabis Scheme	Publicly available here: www.health.govt.nz/about-ministry/information-releases/release-ministerial-decision-making-documents
4	18 March 2021	Aide Memoir HR20210658: Meeting with Rua Bioscience Ltd	Withheld in full under section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

Briefing

Medicinal Cannabis Scheme Transition Period

Date due to MO:	12 February 2021	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	HR 20210223
To:	Hon Andrew Little, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Chris James	Group Manager Medsafe, Health System Improvement and Innovation	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Medicinal Cannabis Scheme Transition Period

Purpose

1. This briefing assesses the issues raised by the transition of the medicinal cannabis scheme to the quality standards and recommends an extension and review.

2. Following discussions with industry on 9 February 2021, and consideration of the benefits and risks, we are recommending a further six months extension to minimise product disruption for patients while supporting an increase in the availability of approved products.

Summary

3. The medicinal cannabis scheme transition to the quality standards system is due to occur on 1 April 2021. While companies agreed to the quality standards during consultation in 2019 and were provided with a further extension to meet information requirements due to COVID-19, it is likely that only one company will have met the information requirements for product verification by 1 April 2021.

4. Patients currently prescribed cannabidiol (CBD) products that do not meet the quality standards will no longer be able to access them from 1 April 2021. Products containing controlled drugs Tetrahydrocannabinol (THC) that do not meet the quality standards will be able to be prescribed with Ministerial approval (with the requirement for specialist recommendation). This will create some accessibility challenges, as there will only be a small range of products.

5. An extension of time would be a temporary solution to allow patients to continue to access a wider range of CBD products at lower costs and assist one further company meet information requirements for an approval. During this time, officials will continue to work with industry to ensure the standards are fit for purpose, and will brief you on the outcome.

6. The benefits and risks of a further extension to the transition period will require clear messaging for patients, prescribers and companies about product quality and the process for them coming to the market.

7. An extension of time will require authorisation for PCO to draft the changes to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

Recommendations:

We recommend you:

a) **Note** stakeholders widely agreed to the medicinal cannabis quality standards during consultations in 2019, and companies supported the additional extension to the transition period to meet them by 1 April 2021. **Noted**

b) **Note** that only one company has provided information necessary for a decision to be made on verification of their medicinal cannabis product against the quality standards by 1 April 2021. **Noted**

c) **Note** that that balancing disruption to patient access and supporting a fair business environment means that an extension of no more than six months should be granted. **Noted**

d) **Agree** to the preparation of a Cabinet paper seeking an extension of the quality standards coming into force for another six months, from 1 April to 1 October 2021. **Yes/No**

e) **Note** that during this time we will be continuing to discuss the standards with industry to ensure they are fit for purpose and will brief you on the outcome. **Noted**

Maree Roberts
Deputy Director General
System Strategy and Policy
Date: 12/2/21

Hon Andrew Little
Minister of Health
Date:

Medicinal Cannabis Scheme Transition Period

Background

8. The government made a commitment in 2017 to improve access to medicinal cannabis, and this has been enabled through the introduction of the Medicinal Cannabis Scheme and the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. The scheme came into effect on 1 April 2020 with a transitional period of six months to ensure that patients could continue to access existing medicinal cannabis products while suppliers submitted applications for verification against the minimum quality standards.

9. The transitional period was extended for a further six months to 1 April 2021 to allow for suppliers experiencing difficulties in arranging for the required product testing due to COVID-19. Despite the initial transition period and subsequent extension, some companies have failed to provide the information required for their products. A number of companies were also rejected on the basis that the product was not made under Good Manufacturing Practice standards.

10. An article was published by the NZ Herald on 5 February 2021 titled "New Zealand's medicinal cannabis supply in jeopardy" that highlighted that no medicinal cannabis products had yet been approved. The article expressed concern that patients will be unable to access medicinal products at all or will only be able to access a limited range of medicinal cannabis products at a high price.

11. The Medicinal Cannabis Authority discussed the NZ Herald article and the industry's views on the standards with the New Zealand Medicinal Cannabis Council (NZMCC) at their Board meeting on 9 February. The NZMCC advised (verbally) that they continue to support the manufacturing requirements with respect to medicine Good Manufacturing Practice (GMP) and a number of companies have invested heavily to achieve that standard.

12. It is likely that only one company will have medicinal cannabis products that meet the minimum quality standard by 1 April 2021, and that one more company may also have product approved within a further six months.

Analysis

Quality standards for medicinal cannabis products

13. The standard for medicinal cannabis products under the Medicinal Cannabis Scheme is different to that of medicines under the Medicines Act 1981; there are no requirements to supply clinical data and no assessments to demonstrate the efficacy and safety of the products. The Medicinal Cannabis Scheme sets a more attainable bar for medicinal cannabis products to support greater access, while still providing a robust safety framework (Sativex is the only cannabis product to be approved as a medicine by Medsafe). There is also a significant price difference in products that are required to meet the more stringent medicines standards.

14. The standard for medicinal cannabis products was consulted on, and widely supported, in 2019. The standard medicinal cannabis products must meet is GMP which aligns internationally with Australia, Japan and those in the European Union. Medicinal cannabis products must also be supported by information that verifies minimum product standards – assessed by the Medicinal Cannabis Authority. The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 sets out the product specifications and requirements for testing, and suppliers must provide evidence that products have been tested in accordance with the test methods, specifications and limits.

15. The requirement for assessment against the minimum quality standards is to protect patients against product contamination (for example, with pesticides and heavy metals) and to provide assurance to medical practitioners about the quality, consistency and stability of such products. Providing this assurance for medical practitioners was also a key factor in support for GMP as the manufacturing standard. There is a cost associated with having these standards and they are more expensive than products that would not meet standards.

16. There are a wide range of views about regulating quality standards for medicinal cannabis products. These can range from almost no regulation based on the view that its relative harms and risks and can be managed without strong oversight, to the view that if it is a medicine and a controlled substance it should be strictly regulated as one. New Zealand's regulatory controls for medicinal cannabis seek to balance product quality, access and risks by setting appropriate standards that can be steadily reviewed by the Medicinal Cannabis Agency. From 1 April 2021, access to medicinal cannabis products will become limited under the current settings (see Table 1 below). Note that people using cannabis for palliation (with less than 12 months to live) are not committing an offence using any cannabis under the Misuse of Drugs Act 1975.

Table 1 – Access to Medicinal Cannabis products

Medicinal Cannabis	**Pre-1 April**	**post-1 April (no extension)**	**post 1-April (with extension)**
CBD only products	Range of products Prescription only medicine (includes unapproved products) Can be prescribed by all doctors	One product available for prescribing Can be prescribed by all doctors. (Unapproved products can be imported by medical practitioner for named patients or a pharmacy on their behalf)	Unapproved products continue to be available on prescription for six months then possible one + approved products (Unapproved products can be imported by medical practitioner for named patients or a pharmacy on their behalf)

THC products	Prescription only medicine (includes unapproved products) Can be prescribed by all doctors	One product available for prescribing (other unapproved products may still be prescribed with a specialist recommendation and Minister approval (delegated to the Ministry)	At least one product available for prescribing – unknown if there will be more (other unapproved products may still be prescribed with a specialist recommendation and Minister approval (delegated to the Ministry)

17. It is anticipated that only one company will have products approved by 1 April 2021 (one CBD and one THC). These products are likely to be more expensive than the outgoing unapproved products due to the higher standards that the approved products adhere to. We therefore recommend that the transitional period is extended for a further six months to allow patients to continue to access a wider range of CBD products at lower costs.

18. Should you agree to the extension, we will continue to discuss the standards with industry to ensure that they are fit for purpose and will brief you on the outcome.

Equity

19. Some patients and prescribers will consider the requirement for specialist recommendation a barrier to equitable access to medicinal cannabis for disadvantaged groups. While the requirement for specialist recommendation has been seen as a barrier to access, healthcare professionals have indicated a preference to continue the requirement for unassessed products due to concerns about the safety and efficacy of low-quality products. Keeping the current requirements would ensure that unassessed products would not be frequently prescribed outside of exceptional circumstances.

There are benefits and risks in deciding whether to further extend the transition period

20. Benefits of a further extension include:

    a. ensuring patients currently receiving medicinal cannabis products will be able to continue to do so at present costs

    b. further discuss with industry the standards to ensure their fitness for purpose

21. Risks of a further extension include:

    a. setting an expectation that lower standard products are an acceptable risk

    b. providing an unfair market advantage to those companies that have not complied with the standards

c. even though an extension is granted there may be only a couple or no new products approved.

22. Benefits of not granting an extension include:

a. setting clear expectations for industry about compliance with the standards

b. ensuring a fair commercial playing field

c. ensuring only those products that meet the standard are available.

23. Risks of not granting an extension include:

a. Patients who may not be able to afford approved products and miss out or turn to the illicit market (ongoing risk)

b. The government's goal of increased access is not fulfilled in the short term

24. The transition to a medicinal cannabis will that meets quality and access requirements will continue to take time as companies set up business and cultivation starts. 34 supply and cultivation licenses have been granted, but products will still need to proceed through same GMP and minimum quality verification processes.

25. On balance, and putting the patient first, an extension of time will best serve some of the immediate health needs of New Zealanders while more products are approved.

ENDS

Briefing

Cabinet paper to further extend the transitional period for the medicinal cannabis scheme

Date due to MO:	3 March 2021	**Action required by:**	3 March 2021
Security level:	IN-CONFIDENCE	**Health Report number:**	20210451
To:	Hon Andrew Little, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Chris James	Group Manager Medsafe, Health System Improvement and Innovation	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Cabinet paper to further extend the transitional period for the medicinal cannabis scheme

Security level:	IN CONFIDENCE	**Date:**	3 March 2021
To:	Hon Andrew Little, Minister of Health		

Purpose of report

1. This briefing provides you with a Cabinet paper for consultation with your ministerial colleagues.
2. The paper seeks agreement from Cabinet to a regulation change that will extend a transitional period exempting certain medicinal cannabis products from meeting minimum quality standards, from 31 March 2021 to 30 September 2021.
3. We also seek authorisation to instruct the Parliamentary Counsel Office to draft the minor amendment regulations to be submitted alongside the Cabinet paper.

Recommendations

We recommend you:

a) **Note** that this briefing attaches a Cabinet paper for consultation with your ministerial colleagues. The paper seeks agreement to extend the transitional period exempting certain medicinal cannabis products from meeting minimum quality standards, from 31 March 2021 to 30 September 2021

b) **Note** that in order to get regulation changes made before 31 March 2021, we are proposing to:

- seek both the policy decision to extend the transitional period, and authorisation to submit regulations to Executive Council from Cabinet
- undertake interagency consultation on the paper at the same time as ministerial consultation
- ask you to authorise the Ministry of Health to instruct the Parliamentary Counsel Office to develop the minor amendment regulations to be submitted alongside the Cabinet paper

c) **Authorise** the Ministry of Health to instruct the Parliamentary Counsel Office to draft a minor amendment to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and the Medicines Regulations 1984 to extend the transitional period from 31 March 2021 to 30 September 2021. **Yes/No**

Maree Roberts
Deputy Director-General
System Strategy and Policy
Date:

Hon Andrew Little
Minister of Health
Date:

Cabinet paper to further extend the transitional period for the medicinal cannabis scheme

Background

1. On 12 February 2021 we provided you with a briefing *Medicinal Cannabis Scheme Transition Period* [HR#20210223] which advised that:
   a. the transition period for the medicinal cannabis scheme is due to expire on 31 March 2021, when quality standards will apply
   b. only one company is expected to have met the requirements for product verification against the standards by 31 March 2021
   c. patients who rely on medicinal cannabis will see their access to other companies' products restricted if the transition period is not extended.
2. You agreed that a Cabinet paper should be prepared seeking agreement to extend the transition period for the quality standards to come into force for another six months, from 1 April 2021 to 30 September 2021.

We have provided a draft Cabinet paper for ministerial consultation

3. We have developed a Cabinet paper for consultation with your ministerial colleagues.
4. Timeframes to get a decision will be tight because the regulation change needs to be made before 31 March 2021.
5. Because of this, we are proposing that:
   a. you seek from Cabinet both the policy decision to extend the transitional period, and the authorisation to submit regulations to Executive Council, rather than seeking the policy decision from Cabinet Social Wellbeing Committee first
   b. interagency consultation on the paper will happen at the same time as ministerial consultation
   c. you will authorise the Ministry of Health to instruct the Parliamentary Counsel Office to develop the required regulations to be submitted alongside the Cabinet paper.
6. The agencies that we plan to consult on the Cabinet paper are: the Ministry of Justice, New Zealand Police, New Zealand Customs Service, and the Department of the Prime Minister and Cabinet.

7. The table below summarises the steps and dates required to get the paper to Cabinet on Monday 8 March.

Action	**Date**
PCO instructed, amendment regulations drafted	3 March, 3-5 March 2021
Interagency consultation	3 March 2021 – 5 March 2021
Late lodgement for consideration by Cabinet	5 March 2021
Cabinet consultation	8 March 2021
Regulations approved by Executive Council	15 March 2021

Next steps

8. We will instruct the Parliamentary Counsel Office to draft changes immediately following your authorisation.

ENDS.