In-Confidence

Office of the Minister of Health

Chair, Cabinet Legislation Committee

Amending the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 to further extend the transitional period for the Medicinal Cannabis Scheme

Proposal

1 This paper seeks agreement to:

1.1 extend a transitional period that exempts certain medicinal cannabis products from meeting minimum quality standards until 30 September 2021, and

1.2 submit amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and the Medicines Regulations 1984 to Executive Council to give effect to this extension.

Policy

2 The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) came into effect on 1 April 2020. The Regulations include minimum quality standards for medicinal cannabis products and ingredients. Suppliers of medicinal cannabis products must provide evidence to the Medicinal Cannabis Agency (the Agency) that their products meet the minimum quality standard before they can be supplied in New Zealand.

3 When the Regulations were introduced they included transitional provisions that exempted certain products from meeting minimum quality standards for a six-month period (ending 1 October 2020).

4 These provisions were included to give manufacturers and importers time to verify their products met the quality standard, while also ensuring that patients who were currently accessing these products were able to continue doing so while they were being assessed.

5 No suppliers were able to demonstrate that their products met quality standards before the original deadline of 1 October 2020, due partly to delays caused by COVID-19.

6 Cabinet agreed in September 2020 to extend the transitional period by six months, until 31 March 2021 (CAB-20-MIN-0450 refers). In making this decision Cabinet noted that if the transition period had ended on the original deadline, access to medicinal cannabis products by patients would have been severely restricted due to a lack of approved products.

7 The situation has not improved significantly in the past six months, with officials advising that only two products are likely to be verified before the extended deadline.

Both products are made by the same company. These products are likely to be more expensive than the unapproved products that are currently available.

8 Officials advise that companies have been slow in submitting applications, due in part to the impact of COVID-19 on business operations, and have not been meeting the requirements when they do apply. Reasons applications have been declined include products not meeting Good Manufacturing Practice for Medicines, and insufficient information being supplied about products.

9 As things currently stand, allowing the transitional period to expire on 31 March 2021 would result in the existing supply of medicinal cannabis products being severely restricted.

10 If this were to occur it is likely that doctors and pharmacists would need to import products for their patients themselves, rather than patients being able to access products through a New Zealand based supplier. This would severely restrict access and increase the cost of products to patients, and raise questions from patients and healthcare professionals about the objective of the scheme to improve access for patients to medicinal cannabis products.

11 I therefore propose to amend the Regulations to further extend the transitional period by six months to 30 September 2021.

12 This extension will ensure the current supply of products to patients continues, while allowing manufacturers and suppliers more time to apply to the Agency to verify that their products meet the minimum quality standard.

People who currently access medicinal cannabis products

13 There are no restrictions on who is eligible to be prescribed medicinal cannabis products, as this is a clinical decision that remains with the doctor. There are currently 235 patients that are prescribed THC-based medicinal cannabis products that are controlled drugs.

14 Cannabidiol (CBD) products are not controlled drugs, so the Ministry of Health does not hold information on the number of patients being prescribed CBD products. However, information provided to Medsafe on supply of CBD products indicates that in 2020, an average of 1500 packs of CBD products have been supplied to patients monthly.

Next steps

15 In seeking this extension, I am mindful that the intention of the Regulations is to ensure that quality medicinal cannabis products that meet minimum standards are available, and that extending the transition period delays this outcome.

16 I also note that medicinal cannabis companies agreed to quality standards when they were developed in 2019, and that the Government is supporting the medicinal cannabis industry through:

16.1 Callaghan Innovation, which developed and launched capability roadmaps last year to support the industry to build capability from Seed to Sale, and has provided research and development project grants to five companies with more understood to be in the pipeline

16.2 support from New Zealand Trade and Enterprise.

17 The New Zealand Medicinal Cannabis Council (the industry representative group) has re-confirmed its support for the Medicinal Cannabis Scheme quality standards, including the need to meet the Good Manufacturing Practice standards for medicines.

18 Officials will continue to work with companies to identify any barriers to products meeting the quality standards, and consider whether further actions can be taken to help companies comply.

Changes to other regulations

19 Cannabidiol (CBD) has been scheduled as a controlled drug and is a prescription medicine regulated under the Medicines Act 1981.

20 The corresponding six-month transitional provision for CBD products is included in the Medicines Regulations 1984. The proposed amendment regulations will also extend the six-month transitional period for CBD products in the Medicines Regulations for a further six months.

Timing and 28-day rule

21 A waiver to the 28-day rule is sought in order to ensure the amendments occur before the transitional period ends on 1 April 2021. It is proposed that the amendments to the regulations will come into effect on 30 March 2021.

Compliance

22 The amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations and the Medicines Regulations 1984 are consistent with:

22.1 the principles of the Treaty of Waitangi;

22.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;

22.3 the principles and guidelines set out in the Privacy Act 1993;

22.4 relevant international standards and obligations; and

22.5 the Legislation Design and Advisory Committee's *Legislation Guidelines* (2018 edition).

23 Section 105(1) of the Medicines Act requires that the responsible Minister consult with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations before recommending the making of an Order in Council under section 105. I am satisfied that the consultation

and discussions that occurred with the New Zealand Medicinal Cannabis Council satisfy this requirement.

Regulations Review Committee

24 There are no anticipated grounds for the Regulations Review Committee to draw the amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations or the Medicines Regulations 1984 to the attention of the House under Standing Order 319.

Certification by Parliamentary Counsel

25 The Parliamentary Counsel Office has certified the amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and the Medicines Regulations 1984 as being in order for submission to Cabinet.

Impact Analysis

26 The Regulatory Quality Team at the Treasury has determined that the regulatory proposals in this paper are exempt from the requirement to provide a Regulatory Impact Statement on the basis that they have minor impacts on businesses, individuals or not for profit entities.

Climate Implications of Policy Assessment

27 The Climate Implications of Policy Assessment (CIPA) team was consulted on the previous extension and confirmed that the CIPA requirements did not apply to the proposal as the threshold for significance is not met. The climate implications of this proposal are identical to the previous extension.

Publicity

28 The Ministry of Health will publish information on their website advising healthcare practitioners, industry and consumers of the extension to the transitional period and will also directly advise relevant individual industry stakeholders.

Proactive release

29 I propose proactively releasing this Cabinet paper after final decisions have been taken by Cabinet.

Consultation

30 The Ministry of Justice, New Zealand Police, New Zealand Customs Service, Ministry for Primary Industries, Ministry of Business, Innovation and Employment, the Accident Compensation Corporation, the Treasury, the Department of the Prime Minister and Cabinet and the Parliamentary Counsel Office were consulted during the preparation of this Cabinet paper.

Recommendations

I recommend that Cabinet Legislation Committee:

1 **note** that the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and the Medicines Regulations 1984 contained a transitional provision that exempted certain products from meeting the minimum quality standard requirement for a six-month period (ending 1 October 2020)

2 **note** that no suppliers were able to demonstrate that their products met quality standards by 1 October 2020, due partly to delays caused by COVID-19, and Cabinet extended the transition period to 31 March 2021 to prevent patients from having their access to medicinal cannabis products severely restricted (CAB-20-MIN-0450 refers)

3 **note** that the situation has not improved significantly, with only two products likely to be verified as meeting the minimum quality standards before the extended deadline, and that these are likely to be more expensive than the unverified products that are currently available

4 **note** that section 105(1) of the Medicines Act requires that the responsible Minister consult with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the Regulations before recommending the making of an Order in Council under section 105;

5 **note** the advice of the Minister of Health that this requirement has been met.

6 **agree** to extend the transitional period by a further six months to 30 September 2021

7 **authorise** the submission to the Executive Council of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2021 and the Medicines Amendment Regulations 2021

8 **note** a waiver of the 28-day rule is sought in order to ensure the amendment occurs before the transitional period ends on 1 April 2021

9 **agree** to waive the 28-day rule for the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2021 and the Medicines Amendment Regulations 2021 to come into force

10 **note** that the proposed Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2021 and the Medicines Amendment Regulations 2021 will come into force on 30 March 2021.

Authorised for lodgement

Hon Andrew Little

Minister of Health

LEG-21-MIN-0023

Cabinet Legislation Committee

Minute of Decision

Amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

Portfolio **Health**

On 11 March 2021, the Cabinet Legislation Committee, having been authorised by Cabinet to have Power to Act [CAB-21-MIN-0058]:

1 **noted** that in September 2020, Cabinet:

1.1 noted that the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and the Medicines Regulations 1984 contain a six-month transitional period to allow continued access to medicinal cannabis products for patients while allowing time for industry to undertake the necessary verification for their products;

1.2 noted that the six-month transitional period has been insufficient, due to industry needing to build capability and disruptions from the COVID-19 pandemic and response;

1.3 agreed to extend the transitional period by a further six months until 31 March 2021;

[CAB-20-MIN-0450]

2 **noted** that the situation has not improved significantly, with only two products likely to be verified as meeting the minimum quality standards before the extended deadline, and that these are likely to be more expensive than the unverified products that are currently available

3 **noted** that section 105(1) of the Medicines Act requires that the responsible Minister consult with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the Regulations before recommending the making of an Order in Council under section 105;

4 **noted** the advice of the Minister of Health that this requirement has been met.

5 **agreed** to extend the transitional period by a further six months to 30 September 2021

6 **authorised** the submission to the Executive Council of the:

6.1 Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2021 [PCO 23619/4.0];

6.2 Medicines Amendment Regulations 2021 [PCO 23629/4.0];

7 **noted** that a waiver of the 28-day rule is sought in order to ensure the amendment occurs before the transitional period ends on 1 April 2021

8 **agreed** to a waiver of the 28-day rule for the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2021 and the Medicines Amendment Regulations 2021 to come into force

9 **noted** that the Amendment Regulations will come into force on 30 March 2021.

Gerrard Carter
Committee Secretary

Present:
Hon Chris Hipkins (Chair)
Hon Andrew Little
Hon Poto Williams
Hon Kris Faafoi
Hon Michael Wood (Deputy Chair)
Hon Dr David Clark
Keiran McAnulty, MP (Senior Government Whip)

Officials present from:
Office of the Prime Minister
Officials Committee for LEG