In Confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Medicinal cannabis: Supplementary Order Paper

Proposal

1 This paper seeks Cabinet approval to instruct the Parliamentary Counsel Office to draft a Supplementary Order Paper to amend the Misuse of Drugs (Medicinal Cannabis) Amendment Bill in the Committee of the whole House.

Executive Summary

2 The Government is committed to improving access to medicinal cannabis for people who may benefit.

3 To meet this commitment, I introduced the Misuse of Drugs (Medicinal Cannabis) Amendment Bill (the Bill) in December 2017.

4 The Bill passed its first reading in January 2018, but the Health Committee was unable to reach agreement to recommend that the Bill proceed before it was reported back to the House in July 2018.

5 The Bill is awaiting its second reading.

6 I recommend several changes to the Bill be proposed by Supplementary Order Paper. The recommendations make the Bill more consistent with the principal Misuse of Drugs Act 1975 (the Act), eliminate barriers to its practical implementation, enable easier navigation and understanding of the Act, and reflect concerns raised by submitters.

7 The proposed changes will:

- 7.1 move the proposed exception provision so that it is located with similar provisions that already exist in the Act
- 7.2 allow quality standards to be set for all stages of production and for all relevant products
- 7.3 allow relevant health professionals to more easily find out important information about quality products
- 7.4 control only those substances found in cannabis that are related to the main psychoactive component of cannabis, and are capable of producing a psychoactive effect

7.5 allow cannabidiol (CBD) products to contain cannabinoids that are not capable of producing a psychoactive effect and a small amount of cannabinoids that are capable of producing a psychoactive effect

7.6 increase the number of people eligible to use the exception by replacing the references to terminal illness in the exception and statutory defence provisions with references to palliation

7.7 allow a licence holder under the medicinal cannabis scheme to use locally sourced cannabis plants, fruit, and seeds

7.8 require regulations on the quality standards to be made no later than a year after the Bill comes into effect.

8 The proposed amendments do not represent a substantial change in policy.

Background

9 Currently, there is a legal pathway for people to obtain medicinal cannabis products on prescription from a medical practitioner. However, access to affordable medicinal cannabis products remain problematic for many New Zealanders.

10 The Government made a 100-day commitment to introduce legislation to make medicinal cannabis available for people with a terminal illness or who are in chronic pain.

11 In November 2017, Cabinet agreed to introduce a medicinal cannabis scheme, and to the following amendments to the Misuse of Drugs Act 1975 [CBC-17-MIN-0043 refers].

12 As a result, I introduced the Misuse of Drugs (Medicinal Cannabis) Amendment Bill on 20 December 2017, which passed its first reading on 30 January 2018.

13 The Bill:

13.1 introduces an exception and a statutory defence for terminally ill people with less than 12 months to live, to possess and use illicit cannabis and to possess a cannabis utensil
13.2 provides a regulation-making power to enable the setting of standards that products manufactured, imported or supplied under licence must meet
13.3 deschedules CBD so it is no longer a controlled drug.

14 The Scheme, overseen by an agency, will result in medicinal cannabis products being able to be commercially produced in New Zealand and, if the Bill is passed, ensure that all medicinal cannabis products meet quality standards. All stages of cultivation, production and supply of medicinal cannabis will be licenced. The Act already provides for the licensing of these activities.

Recommended changes to the Bill

15 After carefully considering the 1786 submissions received on the Bill and hearing 158 oral submissions, the Health Committee was unable to reach agreement. As a

result, the Health Committee could not recommend that the Bill proceed when it reported back to the House on 25 July 2018.

16 I propose that changes, outlined below, are made to the draft Bill through a Supplementary Order Paper. These changes were recommended to the Health Committee during its deliberation on the Bill or emerged during coalition consultation. The proposals do not represent a substantial change in the policy previously agreed by Cabinet.

The exception and statutory defence provision

17 I propose amending the Bill to expand the group of people that will be eligible for the exception and statutory defence provisions. Under this change people requiring palliation will be eligible. Palliation means an approach that aims to alleviate pain and suffering for a person with an advanced progressive life limiting condition, who is nearing end of life. It is the care or medical treatment of a condition that reduces pain without curing the underlying condition.

18 The amendment removes the 12 month restriction and the term 'terminally ill' from the Bill. It is not possible to predict with complete accuracy the progression of life threatening conditions. In addition, 'terminally ill' is no longer commonly used in palliative care and can be confronting for some patients.

19 This definition would cover the approximately 25,000 New Zealanders who could benefit from palliative care, though it is not known how many would choose to use illicit cannabis. I consider 'palliation' better captures the group of patients for whom the provisions were designed.

20 As with the previous definition of 'terminally ill', doctors and nurse practitioners will use their clinical judgement when determining whether a patient is eligible under these provisions. The Ministry will develop guidance for clinicians and the public to support implementation of these provisions.

21 Consequently in clause 5, I propose replacing references to terminal illness with references to requiring palliation.

22 I propose to move the exception for people requiring palliation to be able to possess and use cannabis to section 8 of the Act. This would make the location of the exception consistent with other similar provisions set out in section 8 of the principal Act, and make the Act easier to navigate and understand.

23 The change proposed in paragraph 22 was recommended by the Legislation Design and Advisory Committee.

Setting quality standards

24 Currently, the Bill allows the setting of quality standards that all products manufactured, imported or supplied under a licence granted under the Act must meet.

25 I propose amending clause 7 of the Bill (which would amend section 14 of the Act) to allow the regulations to also prescribe standards for all stages of cultivation,

production, and manufacture. I also propose adding criteria for when the regulations will apply. The technical detail of the standards will be published by the Director-General of Health.

26 This proposal may impose compliance costs for industry, which may be passed on to patients. However, this proposal better reflects the policy intent approved by Cabinet to ensure products are consistently of an acceptable quality and can be prescribed with more confidence.

27 The Ministry will carry out public consultation on the proposals for the regulations.

28 I propose an amendment to require regulations are made no later than a year after the Bill comes into force. This amendment is intended to assure the public and stakeholders that the medicinal cannabis scheme is a priority for the Government.

Making product information available

29 I propose adding a new clause to make it clear that regulations made under section 37(1)(o) of the Act are intended to override section 20 of the Medicines Act 1981.

30 This new clause would allow the Director-General of Health to communicate important information about medicinal cannabis products that meet the scheme's quality standards to appropriate health professionals. Without this clause, it would be difficult for health professionals to know which quality products are available.

31 This will have a negligible impact on industry as they will already need to hold the information to facilitate the use of their products. The proposal is intended to decrease the time health professionals spend researching potential products to prescribe. Individuals may benefit by being able to access quality products more quickly and easily as a result.

32 This approach addresses concerns raised in several submissions to the Health Committee that access would continue to be difficult if health professionals do not know what is available.

Excluding some cannabinoids from control under the Act

33 I propose controlling only those substances that are naturally found in cannabis that are related to tetrahydrocannabinols (THCs), and are capable of producing a psychoactive effect. THCs are a family of largely psychoactive substances that share similar structures and are a subset of the cannabinoid family of substances. The main psychoactive component of cannabis is a THC.

34 The Act currently lists THCs as controlled drugs, and captures a number of other cannabinoids as related substances. A number of these substances have little to no psychoactive effects, and many have potential therapeutic benefits.

35 The amendment is intended for control under the Act to be limited to substances related to THCs that are capable of inducing a psychoactive effect in individuals.

36 I also propose revising the definition of CBD products (clause 4 of the Bill) to allow no more than two percent of the total CBD, THCs and related psychoactive

substances content to consist of THCs and related psychoactive substances that are naturally found in cannabis. This means that where 50 percent of the product is CBD, THCs and related psychoactive substances, no more than one percent of the product can be THCs and related psychoactive substances that are naturally found in cannabis.

37 This would also allow CBD products to contain some non-psychoactive cannabinoids that are naturally found in cannabis.

38 These changes will impose fewer compliance costs for industry in comparison to the provision currently in the Bill because they are less restrictive and easier to comply with. These changes would also enable easier production of CBD products while minimising the risk of harm from psychoactive components that are also naturally found in cannabis.

39 This approach largely addresses concerns raised in numerous submissions to the Health Committee that only psychoactive components of cannabis should be controlled under the Act.

Use of local cannabis varieties

40 This proposal would mean that a person would not be prevented from getting a licence to produce or manufacture a product under the medicinal cannabis scheme only because the variety of plant they propose to use was brought into New Zealand without authorisation, if that variety is now established in New Zealand.

41 The medicinal cannabis scheme will require all stages of cultivation and production to be licensed, there is no obvious reason to preclude varieties of cannabis that are established in New Zealand from being used.

Consultation

42 The Ministry has consulted on amendments as described in 7.1 to 7.5 with the following agencies: Parliamentary Counsel Office, Department of the Prime Minister and Cabinet (PM), New Zealand Police, New Zealand Ministry of Justice, New Zealand Customs Service, Accident Compensation Corporation, Te Puni Kōkiri (Maori Development), The Treasury New Zealand, Ministry for Pacific Peoples, Oranga Tamariki, and PHARMAC.

43 The amendments to change ‘terminal illness’ to ‘palliation’, permit the use of local cannabis varieties, and for quality standard regulations to be made no later than a year after the Bill comes into force, emerged during coalition consultation.

Financial Implications

44 There are financial implications in establishing and operationalising the Scheme. These funding requirements will be considered further in Budget 2019 when detailed cost information is available.

45 It is also proposed to implement a licensing regime for suppliers. Further details regarding this and the fees to be charged will be provided when approval is sought for the associated regulations.

Legislative Implications

46 A Supplementary Order Paper will be required to introduce these changes to the Bill at the Committee of the Whole House.

47 Regulations needed for the Scheme include setting quality standards, allowing limited information about medicinal cannabis products that meet the quality standards to be made available to healthcare practitioners, and setting fees.

48 The Ministry will undertake further analysis, and I will report back on the recommended approach.

Impact Analysis

49 The Regulatory Quality Team has determined that:

49.1 a Regulatory Impact Assessment is not required for proposals 6-8 because they are expected to have no or only minor impacts on businesses, individuals or not-for-profit entities;

49.2 Regulatory Impact Assessment is not required for Proposal 3 as the relevant issues have been covered by existing analysis, in this case the Regulatory Impact Assessment: Medicinal Cannabis prepared by the Ministry of Health https://treasury.govt.nz/publications/risa/regulatory-impact-assessment-medicinal-cannabis.

50 The changes that emerged during coalition consultation to change ‘terminal illness’ to ‘palliation’, permit the use of local cannabis varieties and for quality standard regulations to be made no later than a year after the Bill comes into force, do not materially affect that analysis.

Human Rights

51 The proposals are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Gender Implications

52 There are no gender implications associated with these proposals.

Disability Perspective

53 The intent of the proposed Scheme is to improve access to medicinal cannabis products for patients with significant conditions (for example multiple sclerosis), who do not respond to conventional treatments, as and when the products are available.

Publicity

54 The requirements around access to medicinal cannabis products are complex. It is important that information about access to medicinal cannabis is clearly communicated, realistic expectations are set, and timeframes for achieving domestic cultivation and supply are achievable. I have previously put out a media release,

supported by more information on the Ministry of Health website. I do not intend to put out another media release at this time.

Proactive Release

55 In line with the approach taken with previous Cabinet papers on medicinal cannabis I propose to publish this Cabinet paper on the Ministry of Health website after the Supplementary Order Paper has been tabled in the House during the Committee stage of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill.

Recommendations

The Minister of Health recommends that the Committee:

1. **note** that the Misuse of Drugs (Medicinal Cannabis) Amendment Bill is awaiting its second reading

2. **note** that the Bill:

    2.1. introduces an exception and a statutory defence for terminally ill people to possess and use illicit cannabis and to possess a cannabis utensil

    2.2. provides a regulation-making power to enable the setting of standards that products manufactured, imported or supplied under licence must meet

    2.3. deschedules cannabidiol (CBD) so it is no longer a controlled drug

3. **agree** that amendments to the Bill are proposed via Supplementary Order Paper in Committee of the whole House

4. **authorise** the Minister of Health to issue drafting instructions to Parliamentary Counsel to:

    4.1. move the exception for people requiring palliation to be able to possess and use cannabis to section 8 of the Act

    4.2. amend clause 7 of the Bill to allow regulations to prescribe standards for all stages of cultivation, production, and manufacture, and criteria for when the regulations will apply. The technical detail of the standards will be published by the Director-General of Health

    4.3. add a new clause to make it clear that regulations made under section 37(1)(o) of the Act are intended to override section 20 of the Medicines Act 1981

    4.4. control only those substances naturally found in cannabis that are related to tetrahydrocannabinols (THCs), and are capable of producing a psychoactive effect

    4.5. revise the definition of CBD products to allow no more than two percent of the total CBD, THCs and related psychoactive substances content to consist of

THCs and related psychoactive substances that are naturally found in cannabis

4.6. replace references to terminal illness with references to requiring palliation

4.7. provide that a person would not be prevented from getting a licence to produce or manufacture a product under the medicinal cannabis scheme only because the variety of plant they propose to use was brought into New Zealand without authorisation, if that variety is now established in New Zealand

4.8. amend clause 7 of the Bill to require regulations come into effect no later than a year after this provision of the Bill comes into force

5. **note** that the Ministry of Health will work with Parliamentary Counsel to further refine the wording of the SOP

6. **note** that a draft SOP will be taken to the Cabinet Legislation Committee for consideration for introduction to the House at the Committee of the whole House stage

7. **note** that I have previously advised I will report back to Cabinet to seek agreement on the content of any necessary regulations

8. **note** that I intend to publish this Cabinet paper on the Ministry of Health website following its introduction to the House.

Authorised for lodgement

Hon Dr David Clark

Minister of Health