Health Report number: 20182558

Security classification: In-Confidence

File number: AD62-14-2018
Action required by: n/a

Medicinal Cannabis Amendment Bill Committee of the whole House

To: Hon Dr David Clark, Minister of Health

Purpose

This paper provides speech notes and analysis for the Committee of the whole House stage of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill 2017.

Key points

- The second reading debate on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill took place on 29 November 2018.
- Your second reading speech noted that you intend to table a Supplementary Order Paper on the Bill at the Committee of the whole House stage.
- On Monday 3 December, Cabinet approved the Supplementary Order Paper for tabling.
- Attached as Appendix One are speech notes to inform your initial speech at the start of the Committee of the whole House stage.
- Attached as Appendix Two is a provision by provision analysis of the Bill and proposed changes in the Supplementary Order Paper. You may wish to share this Appendix with colleagues to inform their speeches for the Committee of the whole House stage.
- As Minister in charge of the Bill you will be expected to respond to questions raised by other Members in their speeches on the Bill.

Recommendations

The Ministry recommends that you:

This report is for your information only and does not request any decisions

Todd Krieble
Acting Director-General
System Strategy & Policy

Minister's signature:

Date:

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Medicinal Cannabis Amendment Bill Committee of the whole House

Medicinal Cannabis Amendment Bill

1. The Bill makes three key changes to the Misuse of Drugs Act 1975:
    a. it provides people who have a terminal illness a defence to the charge of possessing and using cannabis
    b. it will allow us to make regulations to set quality standards for medicinal cannabis products
    c. it removes cannabidiol from the Misuse of Drugs Act, so that it is no longer a controlled drug.
2. The Health Committee could not reach agreement on the Bill. As a result, the Bill was reported back to the House on 25 July 2018 with no amendments.
3. The Bill had its second reading on Thursday, 29 November.
4. A number of changes are proposed to improve the Bill through a Supplementary Order Paper (SOP). These changes were recommended to the Health Committee during its consideration of the Bill or emerged during coalition consultation.

Supplementary Order Paper

5. On 29 November 2018, the Cabinet Legislation Committee agreed that a SOP would be tabled at the Committee of the whole House stage of the Bill to:
    a. increase the number of people eligible to use illicit cannabis by replacing the references to terminal illness in the exception and statutory defence provisions with references to palliation
    b. move the exception for people requiring palliation to be able to possess and use illicit cannabis to section 8 of the Misuse of Drugs Act so that it is located with similar provisions that already exist in the Act
    c. 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
    d. control only those substances naturally found in cannabis that are related to tetrahydrocannabinols (THCs), and are capable of producing a psychoactive effect
    e. revise the definition of cannabidiol (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
    f. require regulations to allow the use of cannabis varieties that were previously established in New Zealand without authorisation
    g. require regulations come into effect no later than a year after this provision of the Bill comes into force.
6. The draft version of the SOP included a proposal to change the Bill to make it clear that Agency can inform prescribers of the medicinal cannabis products that meet the quality requirements of the Medicinal Cannabis Scheme.
7. The Office of the Clerk deemed this proposed change to be out of scope of the Bill. While this change would have provided clarity about the Agency's information-sharing ability, the Ministry considers the current legislation already allows the Agency to share with prescribers which products meet the quality standards.
8. The Ministry will update the Medicinal Cannabis Scheme webpage to reflect the changes to the Bill following the Committee of the whole House stage.

Committee of the whole House stage

9. Enclosed as Appendix One are speech notes you may wish to use for your initial speech at the Committee of the whole House stage of the Bill. At this stage the Bill is debated by provision. Your initial speech will be on provision 1 *Title* of the Bill, and outlines the key features of the Bill.

10. The SOP will be discussed when the debate reaches the first provision that the SOP amends. This is provision 4 *Section 2 amended (Interpretation)*. Speeches on provision 4 should focus on the interpretation section of the Bill and the SOP changes to this provision. The remaining changes in the SOP will be considered as part of the consideration of each of the remaining provisions on the Bill that the SOP amends.

11. SOPs from any other Members of the House will be considered on the same basis, first discussed when debate on the first provision amended by a SOP is reached.

12. Members of the House can have up to four five-minute speeches on each provision. As Minister in charge of the Bill, you can have multiple five-minute speeches during this stage. You will be expected to respond to questions raised by other members of the House in their speeches on the provisions in the Bill.

13. Appendix Two is a provision by provision analysis of the Bill and the proposed SOP changes. This information is intended to inform:

    - any speeches you choose to make on the 10 provisions of the Bill; and
    - your response to questions raised by other Members about the Bill throughout the Committee of the whole House stage.

14. If the majority of Parliament votes in support of your SOP, the changes will be incorporated into the Bill. If the majority of Parliament votes in support of the Bill it will go through to its third reading and following that Royal assent.

Proactive release

15. We do not intend to proactively release this paper until the Committee stage of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill is complete.

END.

Appendix One: Speech notes for provision one of the Bill

The Bill will be introduced by the Leader of the House

What the Bill does

This Government is committed to improving access to medicinal cannabis by establishing a Medicinal Cannabis Scheme, and amending the Misuse of Drugs Act 1975.

The Scheme, overseen by an agency, will result in medicinal cannabis products being able to be commercially produced in New Zealand, and ensure that all medicinal cannabis products are of a suitable quality.

The Misuse of Drugs (Medicinal Cannabis) Amendment Bill 2017:

- 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
- provides a regulation-making power to enable the setting of standards that medicinal cannabis products must meet, and
- deschedules cannabidiol also referred to as CBD so it is no longer a controlled drug.

I propose making a number of changes to improve the Bill through a Supplementary Order Paper. These changes will improve the workability of the Bill and reflect concerns raised by submitters.

Support for the Bill

There was overwhelming support from submitters to the Health Committee for the ability to use medicinal cannabis, and for improving access to affordable, quality products.

There was clear support for the development of a Medicinal Cannabis Scheme that ensures products meet a quality standard and enables commercial cultivation and manufacture in New Zealand.

And there was strong support for descheduling cannabidiol (CBD), a substance found in cannabis that has potential therapeutic value, and little or no psychoactive properties.

Appendix Two: Provision by provision analysis of the Bill including proposed Supplementary Order Paper changes

1. **Title**

2. **Commencement** comes into force the day after it receives Royal assent.

3. **Principal Act**

4. **Section 2 of the Bill amended (Interpretation)**

Bill	This provision sets out the definition of cannabidiol (CBD) product and terminal illness.
Amendment proposed via SOP	• Change to the definition of CBD product (and move it to a new provision 2A of the Bill); • Insert a definition of non-psychoactive THC analogue and a definition of specified substance in a CBD product (to support the proposal in the SOP for control under the Act to be limited to THCs and substances related to THCs that are capable of inducing a psychoactive effect in individuals – see provision 9); • Except the non-psychoactive THC analogues that are naturally found in cannabis from being controlled drugs under the Act; and • Change references to terminal illness to references to palliation.

Definition of CBD product

The SOP amends the definition of a CBD product. Currently the definition has a two percent allowance for all other cannabinoids as contaminants, whether they are capable of producing a psychoactive effect or not. This means the current definition includes cannabinoids that are not classified as controlled drugs under the Misuse of Drugs Act.

The proposed change to the definition would allow CBD products to contain some non-psychoactive cannabinoids that are naturally found in cannabis. The two percent allowance in a CBD product would only apply to THCs and substances related to THCs capable of producing a psychoactive effect.

These changes are intended to improve access to CBD products by enabling more products to meet the definition while minimising the risk of harm from psychoactive components that are also naturally found in cannabis.

Definition of palliation

Many submitters on the Bill commented that the exception and statutory defence should be expanded beyond patients who are terminally ill with less than 12 months to live. The Government agrees and the SOP removes ‘terminally ill with less than 12 months to live’ from these provisions and replaces it with ‘palliation’.

Palliation is 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. This a better description of the group of patients the compassionate provisions were designed for.

This change is expected to increase the number of people covered by the exception and statutory defence provisions to the approximately 25,000 New Zealanders who could benefit from palliative care. It is not clear how many would choose to use illicit cannabis.

This is a compassionate approach for people nearing the end of life, where the usual concerns around product safety, quality, efficacy, and long-term risks are different.

4A. **New section 2A inserted (Meaning of CBD product)**

Amendment proposed via SOP	New provision that contains the amended definition of CBD product allowing specified substances up to 2% of the CBD and specified substance content. Specified substances have been defined as: • THCs, and • Substances related to THCs that are capable of producing more than a minor psychoactive effect.

5. **Section 7 amended (Possession and use of controlled drugs)**

Bill	This provision provides an exception and statutory defence for people with a terminal illness to possess and use illicit cannabis.
Amendment proposed via SOP	• Change terminal illness to palliation; and • Move the exception to s8 of the Act (see provision 5A).

The Scheme will take time to develop and implement, and we know that some people with a terminal illness are currently using illicit cannabis. As a compassionate measure, the Bill establishes an exception for people who have been diagnosed with a terminal illness, if they can produce evidence from their doctor or nurse practitioner of their condition. This means they will not be committing an offence if they possess or use cannabis.

This provision of the Bill also provides a defence to a charge of using and possessing cannabis 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.

The SOP would change the Bill to 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. The Government considers 'palliation' better captures the group of patients for whom the provisions were designed.

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 this provision. The Ministry will develop guidance for clinicians and the public to support implementation of this provision.

5A. **Section 8 amended (Exemptions from sections 6 and 7)**

Amendment proposed via SOP	New provision that moves the exception provision 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.

6. Section 13 amended (Miscellaneous offences)

Bill	This provision relates to possessing or using utensils for the purpose of committing an offence under the Act. It provides a defence for people with a terminal illness to possess a cannabis utensil.
Amendment proposed via SOP	Change references to terminal illness to references to palliation.

Possession of a drug utensil is an offence under the Misuse of Drugs Act if it is for the purpose of committing an offence eg, it is used to inhale an illicit drug.

The Bill includes a statutory defence provision for people requiring palliation to possess a cannabis utensil. If a statutory defence provision was not included for possession of a cannabis utensil, there is a risk that a person requiring palliation could be charged and convicted of possession of a utensil. This would be inconsistent with the intent of the exception and statutory defence provisions.

The Bill does not include an exception provision possession of a utensil as a person requiring palliation would not be committing an offence if s/he has a certificate from a medical practitioner or nurse practitioner. Therefore an exception is not needed.

7. Section 14 amended (Licences)

Bill	This provision of the Bill enables regulations to be made to set quality standards for the manufacture, import or supply of medicinal cannabis products.
Amendment proposed via SOP (provision 8A)	• Moves the licensing provision from s14 of the Act to s37A • Enable regulations to also be made to set quality standards for cultivation and production; • Enable regulations to allow a licence holder under the medicinal cannabis scheme to use locally sourced cannabis varieties; • Enable regulations to specify when a product must meet the quality standards; and • Require regulations to be made no later than a year after the Bill comes into effect.

Quality standards

The medicinal cannabis scheme will make it possible for quality medicinal cannabis products to be commercially produced in New Zealand. This provision will ensure that products are made to an acceptable quality standard, so health practitioners can prescribe these products with confidence.

Licensing pathways under the Scheme will allow us to ensure that products meet these standards.

Currently, the Bill allows the setting of quality standards that all products manufactured, imported or supplied must meet. The SOP would change the Bill to enable regulations to also

set standards for all stages of cultivation and production. This will ensure products are consistently of an acceptable quality and can be prescribed with confidence.

The quality standard regulations will only name the standards that must be met. The detail of the quality standards will be published by the Director-General of Health separately. This will allow the Director-General to update the quality standards faster, in response to international developments and sector innovation.

Locally sourced cannabis varieties and regulations within 12 months

The other changes to the regulation provisions in the Bill are to permit licence-holders under the Scheme to use locally sourced cannabis plants, fruit, or seeds and to require regulations to be made within a year of the Bill coming into force.

We will require all stages of medicinal cannabis cultivation and production to be licenced, there is no obvious reason to prohibit the use of varieties that are already established in New Zealand.

Public consultation on quality standards

The proposed product pathways and quality standards and other requirements will be considered as part of the public consultation on the Scheme in the first half of 2019. The ability for patients to be able to access quality medicinal cannabis products is the focus of significant public interest. Patients, the medicinal cannabis industry and health practitioners will provide valuable insights and their input via the consultation process would be an important part of the development of the Scheme.

8. New section 35 E inserted (Review and report on operation of section 7(2A) and (3A))

Bill	This provision requires the Ministry of Health to undertake a review of the operation of the exception and statutory defence provisions.
Amendment proposed via SOP	Changes proposed in this section are only to update references to the relevant clauses in the Act and to update the wording from terminally ill to palliation.

This provision requires the Ministry of Health to undertake a review of the operation of the exception and statutory defence provisions. This is a once-only review due after the provisions have been in force for two years and to be completed within 12 months of the review starting.

9. Schedule 2 amended

Bill	This provision deschedules CBD products from the Act.
Amendment proposed via SOP	Also changes the Schedules of the Act so that it controls substances naturally found in cannabis that are related to THCs, only when they are capable of producing a psychoactive effect.

Descheduling cannabidiol (CBD) products

The Bill deschedules CBD products, so CBD and CBD products are no longer a controlled drug. CBD has potential therapeutic uses and little to no psychoactive effect. There was strong support from submitters to the Health Committee for descheduling CBD.

Descheduling CBD is in line with the advice of the Expert Advisory Committee on Drugs (EACD) who reviewed the classification of CBD in 2016. The EACD advised that, based on their assessment, it would be reasonable to remove CBD from the Act. This would make CBD a prescription medicine only.

The EACD advised that having an allowance of up to two percent of other cannabinoids found in cannabis, in the CBD component of the product, would be appropriate. Naturally-derived CBD products are likely to contain other cannabinoids, such as tetrahydrocannabinols (THCs), as contaminants. The Bill together with the SOP deschedules CBD and CBD products with up to two percent of specified substances, in the CBD component of the product (see section 2 and 2A above).

Excluding some cannabinoids from control under the Act

A number of submitters on the Bill argued that only psychoactive components of cannabis should be controlled under the Misuse of Drugs Act.

The main psychoactive component of cannabis is a tetrahydrocannabinol (THC). THCs are a family of largely psychoactive substances that share similar structures and are a subset of the cannabinoid family of substances.

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

The SOP changes the Bill so that substances that are naturally found in cannabis that are related to THCs, will only be controlled if they are capable of producing a psychoactive effect.

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

10. **Regulations amended**

Bill	This provision makes consequential amendments to the Misuse of Drugs Regulations 1977. All the amendments relate to CBD products.
Amendment proposed via SOP	No changes proposed.

This provision removes the CBD product amendments to the Misuse of Drugs Regulations made in 2017. These changes were made following the Expert Advisory Committee's review of the classification of CBD (see provision 9).

The 2017 amendments to the Regulations removed some of the controlled drug restrictions for CBD products (that contains up to two percent of other cannabinoids found in cannabis). These included changing the period of supply from one month to three, and removing requirements for:

- Ministerial approval to prescribe;
- controlled drug records and stock keeping;
- CBD to be prescribed on a triplicate form;
- CBD products that require refrigeration to be stored in a safe; and

- pharmacies, prescribers, and wholesalers to have an import licence.

As the Bill deschedules CBD products from the Act, the CBD product amendments to the Regulations are no longer necessary.