In Confidence

Office of the Minister of Health

Chair, Cabinet

Misuse of Drugs (Medicinal Cannabis) Amendment Bill 2017: Approval for Introduction

Proposal

1. This paper proposes that the Misuse of Drugs (Medicinal Cannabis) Amendment Bill 2017 be approved for introduction to the House of Representatives.

Policy

- 2. One of the Government's 100-day commitments is to introduce legislation to enable access to medicinal cannabis for people with a terminal illness or chronic pain. This commitment is guided by the principles of equity, quality and safety, and compassion.
- 3. On 6 December 2017, the Cabinet Business Committee [CBC 17 MIN 0043 refers] agreed to amend the Misuse of Drugs Act 1975 (the Act) to:
 - introduce an exception and a statutory defence for terminally ill people to possess and use illicit cannabis
 - provide a regulation-making power to enable the setting of standards that products manufactured, imported, and supplied under licence must meet, and
 - deschedule cannabidiol as a controlled drug.

Exception and statutory defence

- The introduction of an exception and statutory defence is a compassionate measure until affordable quality products are available under the proposed medicinal cannabis scheme.
- 5. The exception means that a person, who has certification from a medical practitioner or nurse practitioner that they are terminally ill, will not commit an offence if they possess or use illicit cannabis for personal use. In this paper illicit cannabis means cannabis that has been grown, processed (ranging from dried leaf material through to oils and balms), and supplied illegally.
- 6. The statutory defence is a defence against prosecution where a person is unable to produce immediate evidence of a terminal illness at the time of questioning by Police, but is able to produce evidence in court.

- 7. The certification from a medical practitioner or a nurse practitioner can be in the form of a letter or written statement. Medical practitioners and nurse practitioners already provide this type of documentation for terminally ill patients to enable life insurance claims and verify sickness leave.
- 8. The statutory defence includes possession of a cannabis utensil. A cannabis utensil is anything that is used as an aid to take illicit cannabis. Possession of a utensil is an offence under the Act if it is for the purpose of committing an offence (the offence being using illicit cannabis). If possession of a cannabis utensil is not included in the statutory defence provision, there is a risk that a terminally ill person could be charged and convicted of possession of a utensil. This would be inconsistent with the intent of the exception and statutory defence provisions.
- 9. The exception provision does not need to include possession of a utensil as a terminally ill person would not be committing an offence if s/he has a certificate from a medical practitioner or nurse practitioner.
- 10.I expect the exception and statutory defence will be the focus of significant public interest. It is likely some stakeholders will want additional patient groups included, and a legal supply route established or the inclusion of cultivation.
- 11. The provisions are limited to terminally ill people. While there are concerns about quality and long-term risks of illicit cannabis use, the circumstances of people with a terminal illness are different. Other patient groups, such as people with chronic pain, are able to access cannabis products via prescription, if their medical practitioner supports its use for that individual. The proposed Medicinal Cannabis Scheme is the mechanism to enable the legal supply of cannabis products.
- 12. There may also be concern that the exception and statutory defence do not cover family/whānau who access cannabis on a terminally ill person's behalf. I do not propose extending the exception and statutory defence to the family/whānau of terminally ill people. Depending on the amount and class of drug, sale and supply can carry significantly higher penalties than possession or use.
- 13. The Bill specifies a review of the provisions two years after they come into force. The review will identify whether the provisions are still necessary following the establishment of the Medicinal Cannabis Scheme.

Enabling product made to a quality standard

- 14. The Bill creates a regulation-making power to enable the setting of standards that products manufactured, imported, and supplied under licence must meet. This will allow the setting of minimum quality standards for both domestically produced and imported cannabis products.
- 15. The ability to set and require minimum quality standards for cannabis products will improve patient safety and give medical practitioners and nurse practitioners confidence about the products available under a Medicinal Cannabis Scheme.

16. The Scheme will enable people, including those with a terminal illness or chronic pain to legally access cannabis products made to a quality standard on prescription from their medical practitioner or nurse practitioner.

Deschedule cannabidiol

- 17. Cannabidiol (CBD) is a substance found in cannabis. The Expert Advisory Committee on Drugs (the Committee who provides expert advice to the Minister of Health on drug classification issues) reviewed the controlled drug classification of CBD in 2016. The Committee advised that CBD has potential therapeutic value, and little or no psychoactive properties, and should be descheduled as a controlled drug.
- 18. The Committee also advised descheduling CBD products with up to two percent of other natural cannabinoids as contaminants. This acknowledges that there is no pure cannabidiol product made to reliable quality standards currently available. Low levels of impurities found in some cannabidiol products are not clinically significant and the scheduling entry should reflect this.
- 19. In line with the Committee's advice, the Amendment Bill will deschedule CBD and CBD products containing up to two percent of other cannabinoids in the total cannabinoid component.

Impact analysis

- 20. An Impact Statement has been prepared and is attached.
- 21. The Regulatory Quality Team at the Treasury has reviewed the Regulatory Impact Statement "Medicinal Cannabis: 100-day action" by the Ministry of Health in accordance with arrangements for 100-day plan priorities.
- 22. The Regulatory Impact Statement sets out the current position as regards the use of cannabis for medicinal purposes and how the proposed legislation is intended to provide comfort for a specific class of users by providing an exception and statutory defence for terminally ill people.
- 23. As noted in the section "Key Limitations or Constraints on Analysis", there is a lack of information about current patterns of usage and demand, including demand that is currently suppressed by legal restrictions, which limits assessment of the likely impacts of lifting those legal restrictions.
- 24. The Regulatory Impact Statement does not analyse the nature and scope of the proposal for a medicinal cannabis scheme. This raises the risk that it may be necessary to reconsider these questions in the course of the detailed design of that scheme, which is to be considered later. It will also be important to monitor and take into account any evidence of changes in demand and supply patterns following the introduction of the exception and statutory defence, in the development and eventual management of the proposed Medicinal Cannabis Scheme.

Compliance

- 25. The Bill is consistent with:
 - 25.1. the principles of the Treaty of Waitangi
 - 25.2. the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993
 - 25.3. the principles and guidelines set out in the Privacy Act 1993
 - 25.4. relevant international standards and obligations, and
 - 25.5. the Legislation Design and Advisory Committee's LAC Guidelines on the Process and Content of Legislation (2014 edition).

Consultation

- 26. The following departments and agencies have been consulted on the policy proposals for the Misuse of Drugs (Medicinal Cannabis) Amendment Bill prior to the 6 December Cabinet Business Committee meeting: DPMC (Policy Advisory Group), PCO, NZ Police, Ministry of Justice, Customs, ACC, Te Puni Kōkiri, Treasury, Ministry of Pacific Peoples, Oranga Tamariki and PHARMAC.
- 27.NZ First and the Green Party were consulted on the policy proposals for the Misuse of Drugs (Medicinal Cannabis) Amendment Bill prior to the 6 December Cabinet Business Committee meeting.
- 28. Treasury, the Ministry of Justice and Police have been consulted on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill.

Binding on the Crown

29. The principal Act binds the Crown.

Creating new agencies or amending law relating to existing agencies

30. No new agencies are created by the Bill.

Allocation of decision-making powers

31. The Bill does not allocate any new decision-making powers.

Associated regulations

32. The Bill creates a regulation-making power to enable standards to be set for any product or class of products, supplied under licence (ie: cultivated, manufactured, and imported).

Other instruments

33. The Bill does not include any provision empowering making of other instruments.

Definition of Minister/department

34. The Bill does not contain a definition of the Minister or department.

Commencement of legislation

35. The Bill will come into force on the day after the date of Royal assent.

Parliamentary stages

- 36. The Bill will need to be introduced by 3 February 2018 to meet the Government's 100-day commitment.
- 37. The Bill should be referred to the Health Committee for consideration.

Recommendations

- 38. The Minister of Health recommends that the Committee:
 - 1. **Note** that the Misuse of Drugs (Medicinal Cannabis) Amendment Bill is not on the 2017 Legislation Programme but is a 100-day commitment.
 - 2. **Note** that the Bill:
 - 2.1 provides an exception and a statutory defence for terminally ill patients to possess and use illicit cannabis and cannabis utensils
 - 2.2 enables the setting of minimum quality standards that products supplied and manufactured under licences must meet, and
 - 2.3 deschedules cannabidiol (CBD) and CBD products with up to two percent of other cannabinoids from the Act.
 - 3. **Approve** the Misuse of Drugs (Medicinal Cannabis) Amendment Bill for introduction, subject to the final approval of the Government caucus and sufficient support in the House of Representatives.
 - 4. **Agree** that the Bill be introduced before 3 February 2018 to meet the Government's 100-day commitment.
 - 5. **Agree** that the Government propose that the Bill be:
 - 5.1 referred to the Health Committee for consideration, and
 - 5.2 enacted by 30 September 2018.

Authorised for lodgement

Hon Dr David Clark

Minister of Health