Misuse of Drugs (Medicinal Cannabis) Amendment Bill

Government Bill

Explanatory note

General policy statement

This Bill amends the Misuse of Drugs Act 1975 (the Act). The Bill will—

- introduce an exception and a statutory defence for terminally ill people to possess and use illicit cannabis and to possess a cannabis utensil; and
- provide a regulation-making power to enable the setting of standards that products manufactured, imported, and supplied under licence must meet; and
- amend Schedule 2 of the Act so that cannabidiol (CBD) and CBD products are no longer classed as controlled drugs.

These measures are part of the new Government's 100-day plan, following the 2017 general election. The measures are intended to improve access to medicinal cannabis and are guided by the principles of fairness, quality and safety, and compassion.

While there is a legal pathway for people to obtain cannabis on prescription from a medical practitioner, access to affordable cannabis products remains problematic for New Zealanders.

The provision of an exception and a statutory defence for terminally ill people to possess and use illicit cannabis and possess cannabis utensils is intended as a compassionate measure until affordable quality products are available under a proposed medicinal cannabis scheme. It is well known that some terminally ill people are choosing to self-medicate with illicit cannabis. The provisions are not intended to encourage terminally ill people to use illicit cannabis, but to exempt from the legal prohibition terminally ill people who possess, use, or intend to use, illicit cannabis.

The Bill also establishes a regulation-making power to set quality standards for domestically manufactured and imported cannabis products. Most cannabis products produced internationally do not meet the quality and efficacy requirements of therapeutic product regulators such as Medsafe. The ability to set and require minimum

quality standards for cannabis products will improve patient safety and give medical practitioners confidence about the available products.

Cannabidiol (**CBD**) is a substance found in cannabis that has potential therapeutic value and few or no psychoactive properties. Removing CBD from Schedule 2, making it a prescription medicine only, reflects the advice of the Expert Advisory Committee on Drugs. The Committee also advised that a CBD product could have an allowed contamination level of other natural cannabinoids of up to 2% of the total cannabinoid content. This acknowledges that no pure cannabidiol product made to reliable quality standards is currently available.

Departmental disclosure statement

The Ministry of Health is required to prepare a disclosure statement to assist with the scrutiny of this Bill. The disclosure statement provides access to information about the policy development of the Bill and identifies any significant or unusual legislative features of the Bill.

A copy of the statement can be found at http://legislation.govt.nz/disclosure.aspx?type=bill&subtype=government&year=2017&no=12

Regulatory impact assessment

The Ministry of Health produced a regulatory impact assessment on 18 December 2017 to help inform the main policy decisions taken by the Government relating to the contents of this Bill.

A copy of this regulatory impact assessment can be found at—

- http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatoryimpact-statements
- http://www.treasury.govt.nz/publications/informationreleases/ris

Clause by clause analysis

Clause 1 is the Title clause. The Title in this case indicates the particular topic of this amendment Bill.

Clause 2 provides that the Bill will commence the day after it receives the Royal assent.

Clause 3 indicates that the Act being amended is the Misuse of Drugs Act 1997 (the **principal Act**).

Clause 4 provides definitions of the terms CBD product and terminal illness. The definition of CBD product is the same as the definition of that term revoked in the Misuse of Drugs Regulations 1977 by the Bill (see clause 10).

Clause 5 amends section 7 of the principal Act to include, as new subclause (2A), an exception to the prohibition set out in subclause (1) for a person who has a certificate from a medical practitioner or nurse practitioner certifying that the person is terminal-

ly ill. *New subclause (3A)* provides that evidence of a diagnosis of terminal illness may be produced as a defence in any proceedings for an offence against section 7.

Clause 6 amends section 13 (which relates to possessing or using certain utensils for the purpose of committing an offence against the Act). The amendment makes it clear that an accused may produce evidence of a diagnosis of a terminal illness.

Clause 7 amends section 14 by enabling regulations to set minimum quality standards for products, or a class of product, that contain a controlled drug and that may be manufactured, imported, or supplied under a licence granted under the Act.

Review of certain provisions

Clause 8 provides for the Minister to require the Ministry of Health to undertake a review of the operation of the exception and defence provisions inserted into the Act by new subclauses (2A) and (3A) of section 7, and to report on their implementation and whether any amendments to those provisions are necessary or desirable. This is a once-only review, to be conducted when these provisions have been in force for 2 years, and must be completed and reported on not later than 12 months from the commencement of the review.

Revocations

Clause 9 provides for the revocation of a number of provisions of Schedule 2, which schedules Class B controlled drugs.

Consequential amendments to Misuse of Drugs Regulations

Clause 10 sets out consequential amendments to the Misuse of Drugs Regulations 1977. All the amendments relate to the status of CBD products.

Hon Dr David Clark

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The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2017.

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This Act comes into force on the day after the date on which it receives the Royal assent.

3 Principal Act

This Act amends the Misuse of Drugs Act 1975 (the **principal Act**).

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4 Section 2 amended (Interpretation)

In section 2(1), insert in its appropriate alphabetical order:

CBD product means a product that—

- (a) contains cannabidiol; and
- (b) if it contains other cannabinoids usually found in cannabis, contains those cannabinoids in a quantity that, in total, constitutes no more than 2% of the total quantity of cannabinoids in the product; and
- (c) does not contain any other controlled drug; and
- (d) does not contain a psychoactive substance (as defined in section 9 of the Psychoactive Substances Act 2013)

terminal illness means an illness from which a person can reasonably be expected to die within 12 months

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

- (1) In section 7(2), replace "subsection (3)" with "subsections (2A) and (3)".
- (2) After section 7(2), insert:

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- (2A) A person who contravenes subsection (1)(a) does not commit an offence if the person—
 - (a) procures, possesses, consumes, smokes, or otherwise uses any plant or plant material of the genus *Cannabis*, any cannabis preparation, or any cannabis fruit or seed; but

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- (b) has a certificate from a medical practitioner or nurse practitioner certifying that the person has a terminal illness.
- (3) After section 7(3), insert:
- (3A) In any proceedings for an offence against subsection (1)(a) in respect of possessing or using any plant or plant material of the genus *Cannabis*, any cannabis preparation, or any cannabis fruit or seed, the defendant may provide evidence that, at the time of the possession or use, the defendant had been diagnosed by a medical practitioner or nurse practitioner as having a terminal illness.
- (4) In section 7(4), replace "subsection (3)" with "subsections (3) or (3A)".
- (5) After section 7(4), insert:

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| 6 Section 13 amended | (Miscellaneous offences) |
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After section 13(1), insert:

(1A) However, in any proceedings for an offence against subsection (1)(a) of possessing a pipe or other utensil (not being a needle or syringe) for the purpose of possessing or using any plant or plant material of the genus *Cannabis*, any cannabis preparation, or any cannabis fruit or seed, the defendant may provide evidence that, at the time of possessing the pipe or other utensil, the defendant had been diagnosed by a medical practitioner or nurse practitioner as having a terminal illness.

7 Section 14 amended (Licences)

After section 14(1), insert:

- (1A) Without limiting subsection (1), the Governor-General may, by Order in Council on the recommendation of the Minister, make regulations to prescribe the minimum quality standard that must be met by a product or class of product—
 - (a) that contains a controlled drug; and
 - (b) that may be manufactured, imported, or supplied under a licence granted under this Act.

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

After section 35D, insert:

Review of certain provisions

35E Review and report on operation of section 7(2A) and (3A)

- (1) The Minister must, not later than 2 years after the commencement of this section, require the Ministry of Health—
 - (a) to commence a review of the operation of section 7(2A) and (3A) since the commencement of those subsections; and
 - (b) to prepare a report on the review for the Minister.
- (2) The review and report required under **subsection (1)** must be completed within 12 months of the review commencing.
- (3) As soon as practicable after receiving the report, the Minister must present a copy of it to the House of Representatives.
- (4) The report on the review must include recommendations to the Minister on—
 - (a) the implementation of the exception and defence provided by section 7(2A) and (3A) for persons who are terminally ill; and
 - (b) whether any amendments to those provisions are necessary or desirable.

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Revocations

9 Schedule 2 amended

- (1) In Schedule 2, Part 1, clause 1,—
 - (a) in the item relating to **Cannabis** preparations, after "material", insert ", other than a CBD product":

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- (b) in the item relating to **Tetrahydrocannabinols**, after "controlled drug", insert "or a CBD product,".
- (2) In Schedule 2, Part 1, clause 2, after "clause 1", insert ", other than cannabidiol (an isomer of tetrahydrocannabinol) and any other isomers of tetrahydrocannabinols when in a CBD product,".

Consequential amendments to Misuse of Drugs Regulations 1977

10 Regulations amended

- (1) This section amends the Misuse of Drugs Regulations 1977.
- (2) In regulation 2, revoke the definition of **CBD product**.
- (3) Revoke regulation 14A (which relates to the authority to import CBD products).
- (4) Revoke regulation 22(2)(c) (which relates to the approval of a CBD product).
- (5) Revoke regulation 28(4)(f) (which provides an exception for CBD products from certain custody requirements).
- (6) Revoke regulation 29(1A) (which exempts the supply of CBD products from 20 certain prescription requirements).
- (7) In regulation 31A(2), delete "or, in the case of a CBD product, 3 months".
- (8) Revoke regulation 48(3) (which disapplies Part 6 in relation to CBD products).

Wellington, New Zealand: