Misuse of Drugs (Medicinal Cannabis) Amendment Bill (No 2)

Member's Bill

Explanatory note

General policy statement

This Bill amends the Misuse of Drugs Act 1975 (the Act). The Bill provides a medicinal cannabis scheme (the scheme) that will—

- license high quality domestic medicinal cannabis production; and
- regulate health practitioner controlled gateway access; and
- facilitate pharmacist dispensing.

This Bill responds to international medicinal cannabis trends by describing a medicinal cannabis scheme for New Zealand that safely and cautiously navigates these waters. This Bill incorporates international observations into a scheme that considers cannabis as a medicine – just like any other medicine, with prescribing clinicians such as doctors and nurse practitioners as the gateway to access. Health professionals are best placed to recommend and advise on eligibility, which will be confirmed with a photo ID Medicinal Cannabis Card. Dispensing will occur at pharmacies after producing the card and following a consultation with the pharmacist. Affordability and availability will be improved by licensing domestic production, utilising existing MedSafe fast track consenting, and regulating pharmacy dispensing.

The medicinal cannabis scheme will not allow loose leaf cannabis. This is consistent with a number of overseas jurisdictions concerned with smoking reduction. The regulated cannabis extract will be manufactured as liquid or pills. Examples of dispensed products include oils, capsules, tablets, and oral sprays.

It is important to note that no part of the scheme normalises or advances recreationalisation or legalisation of cannabis. What the scheme does do is provide a regulated mechanism for available and affordable medicinal cannabis so that clinicians and patients have another set of tools to manage a range of ever increasing conditions.

Clause by clause analysis

Clause 1 is the Title clause.

Clause 2 is the commencement clause. It provides that the Bill comes into force 12 months after the date the Bill receives the Royal assent.

Part 1
Amendments to the Misuse of Drugs Act 1975

Clause 3 provides that the Act amends the Misuse of Drugs Act 1975 (the **principal Act**).

Clause 4 amends section 2 of the principal Act (which relates to interpretation). New definitions, such as, **cannabis for medicinal purposes**, **carer card**, **medicinal cannabis card**, and **medicinal cannabis product**, are inserted.

Clause 5 inserts *new section 3AA* to give effect to *new Schedule 1AA* inserted by clause 12 of the Bill.

Clause 6 amends section 6 of the principal Act (which prohibits dealing with controlled drugs) to provide an exception under *new section 8A*.

Clause 7 amends section 7 of the principal Act (which prohibits the possession and use of controlled drugs) to provide an exception under *new section 8A*.

Clause 8 amends section 8 of the principal Act (which provides exemptions to sections 6 and 7 of the principal Act) to provide that any pharmacist (or any person with the authority and under the immediate supervision of a pharmacist) may produce, manufacture, or supply medicinal cannabis products to medicinal cannabis card holders or carer card holders.

Clause 9 inserts *new section 8A* to provide an exemption that, in accordance with the conditions or restrictions set out in *new Schedule 6*, medicinal cannabis card holders may procure, possess, consume, or use medicinal cannabis products and carer card holders may procure, possess, supply, or administer medicinal cannabis products to a medicinal cannabis card holder.

Clause 10 amends section 14 of the principal Act (which deals with licences) to provide that section 14 applies subject to *new Schedule 7*. *New Schedule 7* applies to licences to cultivate, process, or manufacture cannabis for medicinal purposes.

Clause 11 amends section 37 of the principal Act (which deals with regulations). The amendments extend the purposes for which the Governor-General may, by Order in Council, make regulations to add matters relating to medicinal cannabis cards, medicinal cannabis products, and licences for cannabis for medicinal purposes.

Clause 12 inserts *new Schedule 1AA* into the principal Act. *New Schedule 1AA* provides that the Minister must require the Ministry of Health to review the operation of the Act five years after its commencement and prepare a report for the Minister. The Minister must present a copy of the report to the House of Representatives.

Clause 13 inserts *new Schedule 6* and *new Schedule 7* into the principal Act.

New Schedule 6 provides as follows:

- Clauses 1 to 4 provide for the application for a medicinal cannabis card by a medical practitioner or a nurse practitioner (who are authorised prescribers under the Medicines Act 1981) for a patient in the medical practitioner's or nurse practitioner's care.
- Clauses 5 to 7 provide for the application for a carer card by a medicinal cannabis card holder for a nominated person.
- Clause 8 provides for the Director-General to impose any terms, conditions, or restrictions on medicinal cannabis card holders and carer card holders in relation to the supply, possession, or use of medicinal cannabis products.
- Clause 9 provides for the Director-General to issue cards once an application has been approved.
- Clauses 10 to 12 set out the form of cards and the period of validity of the cards.
- Clause 13 provides for the Director-General to record details of the card holders.
- Clauses 14 to 16 provide for the distribution of medicinal cannabis products to card holders and recording the distribution of medicinal cannabis products.

New Schedule 7 provides as follows:

- Part 1 provides for applying, granting, and issuing licences for cultivating, processing, and manufacturing cannabis for medicinal purposes.
- Part 2 sets out the standard conditions for licences issued under *Part 1*.
- Part 3 provides for the modification, revocation, and suspension of licences.
- Part 4 requires licence holders to submit annual reports to the Director-General every 12 months licence holders hold the licence.
- Part 5 sets out provisions concerning the provisional consent of new medicinal cannabis products and the advertising of medicinal cannabis products.
- Part 6 sets out the offences for breaching the conditions or restrictions of the licence, failing to submit an annual report, and contravening advertising restrictions.

Part 2
Consequential amendments

Clause 14 makes consequential amendments to the Misuse of Drugs Regulations 1977 to remove the requirement to get the Minister's consent to supply medicinal cannabis products.

Clause 15 makes consequential amendments to the Medicines Regulations 1984 to move Cannabidiol and Tetracannabidol from the list of prescription medicines to the list of restricted medicines (more commonly known as pharmacist-only medicine).

This is to ensure that medicinal cannabis products can be supplied by pharmacists as a restricted medicine to medicinal cannabis card holders.

Dr Shane Reti

Misuse of Drugs (Medicinal Cannabis) Amendment Bill (No 2)

Member's Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Misuse of Drugs (Medicinal Cannabis) Amendment Act **(No 2) 2020**.

2 Commencement

This Act comes into force 6 months after the date on which it receives the Royal assent.

Part 1
Amendments to Misuse of Drugs Act 1975

3 Principal Act

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

4 Section 2 amended (Interpretation)

(1) In section 2(1), insert the following definitions in their appropriate alphabetical order:

cannabis means the flowering or fruiting tops of a cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted by whatever name they be designated

cannabis for medicinal purposes means cannabis, a cannabis plant, a cannabis preparation, or cannabis resin, that is grown, cultivated, processed, or manufactured for the purpose of producing a medicinal cannabis product

cannabis plant means—

(a) any plant of the genus *Cannabis*:

(b) any part of a plant of the genus *Cannabis* including, but not limited to, the seeds, stems, or leaves of the plant

cannabis resin means the separate resin, whether crude or purified, obtained from the cannabis plant

carer card means a card issued to a person by the Director-General under **clause 9(1)(c) of Schedule 6**

carer card holder means any person issued with a carer card

corporate body means—

(a) a company:

(b) a partnership:

(c) a body corporate other than a company or partnership

director means,—

(a) in relation to a company, any person occupying the position of a director of the company by whatever name called:

(b) in relation to a partnership, any partner:

(c) in relation to a body corporate other than a company or partnership, any person occupying a position in the body that is comparable with that of a director of a company

Director-General has the same meaning as in section 2(1) of the Medicines Act 1981

medicinal cannabis card means a card issued to a patient by the Director-General under **clause 9(1)(b) of Schedule 6**

medicinal cannabis card holder means any person issued with a medicinal cannabis card

medicinal cannabis product means a finished product of cannabis for medicinal purposes and is a medicine

medicine has the same meaning as in section 3(1) of the Medicines Act 1981

new medicinal cannabis product means a medicinal cannabis product that is a new medicine

new medicine means a new medicine under section 3(3) of the Medicines Act 1981 that does not have the Minister's consent or provisional consent under that Act

nominated person means any person who is nominated by a medicinal cannabis card holder to be a carer card holder to procure, possess, supply, or administer a medicinal cannabis product to the medicinal cannabis card holder

(2) In section 2(1), definition of **prohibited plant**, delete paragraph (a).

5 New section 3AA inserted (Transitional, savings, and related provisions)

After **section 3**, insert:

3AA Transitional, savings, and related provisions

The transitional, savings, and related provisions set out in **Schedule 1AA** have effect according to their terms.

6 Section 6 amended (Dealing with controlled drugs)

In section 6(1), after "section 8", insert "or **8A**".

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

In section 7(1), after "section 8", insert "or **8A**".

8 Section 8 amended (Exemptions from sections 6 and 7)

After section 8(1)(b), insert—

(ba) any pharmacist or any person with the authority and under the immediate supervision of a pharmacist may manufacture, administer, or supply a medicinal cannabis product to a medicinal cannabis card holder, or a carer card holder, in accordance with **Schedule 6**:

9 New section 8A (Medicinal cannabis card exemption from sections 6 and 7)

After section 8, insert:

8A Medicinal cannabis card exemption from sections 6 and 7

Despite sections 6 and 7,—

(a) any medicinal cannabis card holder may procure or possess, or consume, or otherwise use, any medicinal cannabis product in accordance with the conditions and restrictions set out in **Schedule 6**:

(b) any carer card holder may, in accordance with the conditions and restrictions set out in **Schedule 6**,—

(i) procure, possess, or supply any medicinal cannabis product for or to a medicinal cannabis card holder:

(ii) administer any medicinal cannabis product to a medicinal cannabis card holder.

10 Section 14 amended (Licences)

(1) In section 14(1), replace "Licences" with "Subject to **subsection (1A)**, licences"

(2) After section 14(1), insert:

(1A) **Schedule 7** applies to any licences to cultivate, process, or manufacture cannabis for medicinal purposes.

11 Section 37 amended (Regulations)

(1) After section 37(1)(c), insert:

(ca) prescribing circumstances where a contract is not required to be in existence under **clause 15(3)** of **Schedule 7**:

(cb) prescribing the form for the annual report to be submitted, and additional information to be provided, to the Director-General under **clauses 24** and **25** of **Schedule 7**:

(2) After section 37(1)(s), insert:

(sa) prescribing, in relation to medicinal cannabis cards or carer cards,—

(i) any particulars, information, supporting documents, or other material that must accompany or be contained in an application:

(ii) the form of an application:

(iii) any records required under this Act and the method of keeping such records:

(sb) prescribing any information to report to the Director-General on the sale and supply of medicinal cannabis products:

12 New Schedule 1AA inserted

Insert the **Schedule 1AA** set out in **Schedule 1** of this Act as the first schedule to appear after the last section of the principal Act.

13 New Schedules 6 and 7 inserted

After Schedule 5, insert **Schedule 6** and **Schedule 7** set out in **Schedule 2** of this Act.

Part 2
Consequential amendments

14 Misuse of Drugs Regulations 1977 amended

(1) This section amends the Misuse of Drugs Regulations 1977.

(2) After regulation 22(2)(c), insert:

(d) a medicinal cannabis product to a medicinal cannabis card holder or a carer card holder in accordance with **Schedule 6** of the Act.

15 Medicines Regulations 1984 amended

(1) This section amends the Medicines Regulations 1984 (SR 1984/143).

(2) In Schedule 1, Part 1, delete—

(a) "339 Cannabidiol"; and

(b) "1986 Tetrahydrocannabinol".

(3) In Schedule 1, Part 2, after item 10, relating to Butoconazole, insert:

10A Cannabidiol

(4) In Schedule 1, Part 2, after item 78, relating to Sumatriptan, insert:

78A Tetrahydrocannabinol

Schedule 1
New Schedule 1AA inserted

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Schedule 1AA
Transitional, savings, and related provisions

s 3AA

Part 1
Provisions relating to Misuse of Drugs (Medicinal Cannabis) Amendment Act (No 2) 2020

1 Interpretation

In this schedule, **amendment Act** means the Misuse of Drugs (Medicinal Cannabis) Amendment Act (No 2) **2020**.

2 Review of amendment Act

(1) The Minister must, no later than 5 years after the commencement of the amendment Act, require the Ministry of Health—

(a) to commence a review of the operation of the amendment Act since the commencement of the amendment Act; and

(b) prepare a report on the review for the Minister.

(2) The review and report required under **subclause (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—

(a) the number of medicinal cannabis cards and carer cards issued since the commencement of the amendment Act; and

(b) the characteristics of the medicinal cannabis card holders including—

(i) age; and

(ii) gender; and

(iii) ethnicity; and

(iv) the therapeutic purpose for granting medicinal cannabis cards to the holders; and

(c) the number of medicinal cannabis products supplied by pharmacists to medicinal card holders—

(i) in total; and

(ii) in each territorial authority district; and

(d) the number of licences issued under **Schedule 7**; and

(e) the volume and type of cannabis for medicinal purposes distributed by licence holders; and

(f) recommendations to the Minister on—

(i) the implementation of the amendment Act; and

(ii) whether any amendments to the amendment Act are necessary or desirable.

Schedule 2
New Schedules 6 and 7 inserted

s 13

Schedule 6
Medicinal Cannabis

ss 8 and 8A

Contents

Medicinal cannabis card

1 Application for medicinal cannabis card

(1) A medical practitioner or nurse practitioner may apply to the Director-General for a medicinal cannabis card for a patient in the care of that medical practitioner or nurse practitioner.

(2) An application under **subclause (1)** must—

(a) provide the full name, date of birth, gender, and residential address of the patient; and

(b) provide a photographic image of the patient; and

(c) state that the medical practitioner or the nurse practitioner has examined the patient in person; and

(d) state the date of that examination; and

(e) provide information about the underlying medical condition of the patient; and

(f) confirm the patient is eligible in accordance with the criteria prescribed under **clause 2**; and

(g) explain the therapeutic benefit the medical practitioner, or the nurse practitioner, expects the patient to obtain from using a medicinal cannabis product; and

(h) where the patient is under 18 years of age, provide the written permission of the parent or guardian of the patient; and

(i) provide any other information prescribed by regulations.

(3) The application must be in the prescribed form (if any).

2 Eligibility criteria of patient

(1) The Director-General may, by notice in the *Gazette*, prescribe the criteria for assessing the eligibility of a patient under **clause 1(2)(f)**.

(2) The Director-General must, before publishing a notice in the *Gazette* under **subclause (1)**, consult—

(a) the Medical Council of New Zealand; and

(b) the Nursing Council of New Zealand; and

(c) the Royal New Zealand College of General Practitioners; and

(d) any other relevant organisations, groups, or individuals that the Director-General considers have an interest in the eligibility criteria.

(3) The Director-General must ensure that a notice made under **subclause (1)** remains in force at all times.

(4) Nothing in **subclause (3)** prevents a notice made under this clause from being amended or from being revoked and replaced by another notice made under this clause.

3 Approval of application for medicinal cannabis card

(1) The Director-General may approve an application for a medicinal cannabis card if the Director-General is satisfied that the application complies with **clause 1**.

(2) The Director-General may, for the purpose of **subclause (1)**,—

(a) seek and receive any information as the Director-General thinks fit; and

(b) consider information obtained from any source.

(3) Nothing in this clause limits the Privacy Act 1993.

4 Refusal to approve application for medicinal cannabis card

If the Director-General refuses to approve an application under **clause 3**, the Director-General must give the medical practitioner, or nurse practitioner, and the patient written notice of the refusal and the reasons for it.

Carer card

5 Application for carer card

(1) A medicinal cannabis card holder may apply to the Director-General for a carer card to be issued to a nominated person.

(2) An application under **subclause (1)** must—

(a) provide the full name, date of birth, gender, and residential address of the nominated person; and

(b) provide the full name, date of birth, gender, and residential address of the medicinal cannabis card holder; and

(c) provide the unique identifiers of the relevant medicinal cannabis card; and

(d) provide the relationship of the nominated person to the medicinal cannabis card holder; and

(e) explain the reasons for the nominated person to be issued a carer card; and

(f) provide a photographic image of the nominated person; and

(g) state if there are any nominated people who hold carer cards in relation to the medicinal cannabis card holder; and

(h) provide any other information prescribed by regulations.

(3) An application under **subclause (1)** must be in the prescribed form (if any).

6 Approval of application for carer card

(1) The Director-General may approve an application under **clause 5** if the Director-General is satisfied that—

(a) the application complies with **clause 5**; and

(b) the reasons for the nominated person to be issued a carer card are good reasons and is satisfied that those reasons exist in fact.

(2) The Director-General must not approve a carer card if—

(a) the nominated person already holds 5 carer cards; or

(b) the medicinal cannabis card holder already has 5 nominated persons that have been issued carer cards.

(3) The Director-General may, for the purpose of **subclause (1)**,—

(a) seek and receive any information that the Director-General thinks fit; and

(b) consider information obtained from any source.

7 Refusal to approve application for carer card

If the Director-General refuses to approve an application under **clause 6**, the Director-General must give the medicinal cannabis card holder and the nominated person written notice of the refusal and the reasons for it.

Terms, conditions, or restrictions on card holders

8 Terms, conditions, or restrictions on card holders

The Director-General may impose any term, condition, or restriction in relation to the supply, possession, or use of medicinal cannabis products on a medicinal cannabis card holder or a carer card holder.

Issuing cards

9 Issuing cards

If the Director-General approves an application under **clause 3** or **clause 6**, the Director-General must, as soon as practicable,—

(a) give the medical practitioner or the nurse practitioner, the medicinal cannabis card holder, and the carer card holder (as applicable), written notice specifying the date on which the medicinal cannabis card, or carer card, takes effect and the period the medicinal cannabis card, or carer card, is valid; and

(b) issue and send the medicinal cannabis card to the patient; and

(c) issue and send the carer card to the nominated person; and

(d) give the medical card holder and the carer card holder written notice of the additional terms, conditions, or restrictions imposed on them under **clause 8**.

Form of cards

10 Medicinal cannabis card

A medicinal cannabis card must be in the prescribed form and include—

(a) a photographic image of the medicinal cannabis card holder; and

(b) the medicinal cannabis card holder's name; and

(c) the medicinal cannabis card holder's date of birth; and

(d) the medicinal cannabis card holder's residential address; and

(e) unique identifiers to distinguish the medicinal cannabis card and the holder from other medicinal cannabis cards and holders; and

(f) the original date of issue of the medicinal cannabis card; and

(g) the date on which the medicinal cannabis card expires; and

(h) any terms, conditions, or restrictions on the medicinal cannabis card holder; and

(i) any other information that may be prescribed by regulations.

11 Carer card

A carer card must be in the prescribed form and include—

(a) a photographic image of the carer card holder; and

(b) the carer card holder's name; and

(c) the carer card holder's date of birth; and

(d) the carer card holder's residential address; and

(e) the name of the relevant medicinal cannabis card holder; and

(f) the relationship of the carer card holder to the relevant medicinal cannabis card holder; and

(g) unique identifiers to distinguish the card and the holder from other carer cards and holders; and

(h) the original date of issue of the carer card; and

(i) the date on which the carer card expires; and

(j) any terms, conditions, or restrictions on the carer card holder or the relevant medicinal cannabis card holder; and

(k) any other information that may be prescribed by regulations.

12 Period of validity for cards

(1) A medicinal cannabis card is valid for a maximum of 12 months from the date of issue.

(2) A carer card is valid for the duration the relevant medicinal cannabis card is valid.

(3) Before the expiry of a medicinal cannabis card, a medical practitioner or a nurse practitioner may reapply under **clause 1** for a medicinal cannabis card for the patient.

(4) Before the expiry of a carer card, a medicinal cannabis card holder may reapply under **clause 5** for a carer card for the nominated person.

Registration of card holders

13 Recording card holders

(1) If the Director-General issues a medicinal cannabis card, or a carer card, under **clause 9**, the Director-General must record—

(a) the full name, date of birth, gender, and the residential address of the medicinal cannabis card holder; and

(b) in relation to every medicinal cannabis card holder, the full name, date of birth, gender, and the residential address of the carer card holder (as applicable); and

(c) the date each card is issued and the date it expires; and

(d) the photographic image of each card; and

(e) the unique identifiers of each card; and

(f) the information provided in the application under **clause 1** including:

(i) name of the medicinal practitioner or nurse practitioner that examined the medicinal cannabis card holder; and

(ii) the information about the eligibility of the medicinal cannabis card holder to use a medicinal cannabis product; and

(iii) the information about the expected therapeutic benefit for the patient to obtain from using a medicinal cannabis product; and

(g) the information provided in the application under **clause 5** (as applicable) including:

(i) the relationship of the carer card holder to the medicinal cannabis card holder; and

(ii) the reasons issuing a carer card to the carer card holder; and

(h) any other particulars that may be prescribed in regulations.

(2) The Director-General must keep the records in the prescribed method and must retain them for the prescribed period.

Supply, administering, or prescribing of medicinal cannabis products

14 Therapeutic benefit of medicinal cannabis products

Before supplying, administering, or prescribing a medicinal cannabis product, a medical practitioner, nurse practitioner, or pharmacist must be satisfied that the medicinal cannabis product is for the medicinal cannabis card holder's therapeutic benefit.

15 Form of medicinal cannabis products

(1) A medical practitioner, nurse practitioner, or pharmacist must not supply, administer, or prescribe a medicinal cannabis product if—

(a) the medicinal cannabis card holder must smoke it; or

(b) it is botanical cannabis.

(2) Subject to **subclause (1)**, a medical practitioner, nurse practitioner, or pharmacist may supply, administer, or prescribe a medicinal cannabis product if it is —

(a) a liquid, including, but not limited to, oil:

(b) a pill:

(c) a vaporised delivery method with use of liquid or oil:

(d) in any other form prescribed by regulations.

(3) In this section,—

botanical cannabis means unprocessed or non-standardised leaf or flower preparations from a cannabis plant

to smoke means to smoke, hold, or otherwise have control over an ignited cannabis or cannabis plant.

16 Reporting sales or supply of medicinal cannabis products

A medical practitioner, nurse practitioner, or pharmacist that supplies, administers, or prescribes a medicinal cannabis product must, as soon as practicable after the end of every month in which they have supplied, administered, or prescribed such medicinal cannabis product, report that sale or supply to the Director-General in writing, with the following information:

(a) the name and details of the medicinal cannabis card holder; and

(b) the name and details of the carer card holder (if applicable); and

(c) the description of the medicinal cannabis product; and

(d) the description of the occasion when and where the medicinal cannabis product was supplied, administered, or prescribed; and

(e) any other information prescribed by regulations.

Schedule 7
Cannabis for medicinal purposes licence

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Contents

Part 1
Application and eligibility for licences

Application for licence

1 Application for licence to cultivate or process cannabis for medicinal purposes

(1) A person may apply to the Director-General for a licence that authorises 1 or more of the following activities:

(a) cultivating cannabis plants for the purpose of producing cannabis for medicinal purposes:

(b) obtaining cannabis plants for the purpose of cultivating cannabis for medicinal purposes:

(c) processing cannabis for medicinal purposes:

(d) activities relating to obtaining, cultivating, or processing cannabis for medicinal purposes.

(2) If the applicant is a corporate body, the corporate body must nominate 1 or more individual to be the responsible person.

(3) The application must be made in the prescribed form, and must contain the information and supporting evidence prescribed by the regulations.

(4) The application must be accompanied by the application fee (if any) prescribed by the regulations.

2 Application for licence to manufacture cannabis for medicinal purposes

(1) A person may apply to the Director-General for a licence that authorises 1 or more of the following activities:

(a) manufacturing of cannabis for medicinal purposes:

(b) activities relating to manufacturing cannabis for medicinal purposes, including, but not limited to, the following (as applicable):

(i) the supply:

(ii) the packaging, transport, storage, possession, and control:

(iii) the disposal or destruction.

(2) If the applicant is a corporate body, the corporate body must nominate 1 or more individuals to be the responsible person.

(3) The application must be made in the prescribed form, and must contain the information and supporting evidence prescribed by the regulations.

(4) The application must be accompanied by the application fee (if any) prescribed by the regulations.

Granting a licence

3 Director-General to determine application for a licence

(1) The Director-General may approve an application if the Director-General is satisfied that—

(a) the applicant is eligible under **clause 4(1)** or **5(1)** to hold the licence sought; and

(b) the applicant is a suitable person under **clause 4(2)** or **5(2)** to hold the licence sought; and

(c) the individual named in the application is eligible under **clause 6(1)** and is a suitable person under **clause 6(2)** to be the responsible person; and

(d) the location specified in the application is safe in accordance with **clause 7**; and

(e) the applicant will comply with the standard conditions in **Part 2** and any other conditions or restrictions that may be imposed under **clause 8**; and

(f) the licence is for commercial, not personal, production; and

(g) there is a need for commercial supply and demand for cannabis for medical purposes.

(2) If the Director-General decides not to grant an application, the Director-General must notify the applicant of the decision and of the reasons for the decision.

(3) If the Director-General approves an application, the Director-General must issue a licence in accordance with **clause 9**.

Eligibility for licence

4 Eligibility and suitability for an individual to hold a licence

(1) An individual is eligible to hold a licence if the person—

(a) is 18 years or older; and

(b) has not been convicted of—

(i) an offence against this Act or of any other drug-related offence; or

(ii) a crime involving dishonesty as defined in section 2(1) of the Crimes Act 1961; or

(iii) an offence punishable by imprisonment for 2 or more years; or

(iv) an offence outside New Zealand that, if committed in New Zealand, would fall within **subparagraph (i)**, **(ii)**, or **(iii)**; and

(c) has not, at any time, been addicted or habituated to the use of a controlled drug, prescription medicine, or restricted medicine; and

(d) has not, at any time, been declared bankrupt or been a director of a corporate body that has been put into receivership or liquidation; and

(e) has not had a licence under this Act that has been revoked at any time in the 5 years preceding the date of their application; and

(f) is entitled to use the location or locations specified in the application for the activities for which the licence is sought; and

(g) has the expertise and the resources to undertake the activities for which the licence is sought; and

(h) is familiar with, and has the expertise and the resources to comply with, the obligations imposed on a licence holder of a licence of the kind sought by the application.

(2) In determining whether a person is suitable to hold a licence, the Director-General may consider—

(a) the connections and associations that the person has with other persons who may have the ability to influence the conduct of the person:

(b) the person's previous business experience:

(c) whether the person has financial circumstances that may significantly limit the person's capacity to comply with their obligations under a licence:

(d) the person's reputation, having regard to matters going to their character, honesty, and professional and personal integrity:

(e) any other matters the Director-General considers relevant.

(3) In order to ascertain whether an applicant has a conviction of the kind specified in **subclause (1)(b)**, the Director-General may ask the New Zealand Police to check if any of those persons has a conviction of that kind.

5 Eligibility and suitability for a corporate body to hold a licence

(1) A corporate body is eligible to hold a licence if—

(a) every director of the corporate body is 18 years or older; and

(b) the corporate body, or any director of the corporate body, has not been convicted of—

(i) an offence against this Act or of any other drug-related offence; or

(ii) a crime involving dishonesty as defined in section 2(1) of the Crimes Act 1961; or

(iii) an offence punishable by imprisonment for 2 or more years; or

(iv) an offence outside New Zealand that, if committed in New Zealand, would fall within **subparagraph (i)**, **(ii)**, or **(iii)**; and

(c) every director of the corporate body has not, at any time, been addicted or habituated to the use of a controlled drug, prescription medicine, or restricted medicine; and

(d) every director of the corporate body has not, at any time, been declared bankrupt or been a director of a corporate body that has been put into receivership or liquidation; and

(e) no licence held by the corporate body or the director of the corporate body under this Part has been revoked at any time in the 5 years preceding the date of their application; and

(f) the corporate body is entitled to use the location or locations specified in the application for the activities for which the licence is sought; and

(g) the corporate body has nominated 1 or more individuals to be responsible persons, being individuals who are eligible under **clause 6**; and

(h) 1 or more directors of the corporate body, or employees of the corporate body, have the expertise—

(i) to comply with the obligations imposed on a licence holder of a licence of the kind sought by the application; and

(ii) to undertake the activities for which the licence is sought; and

(i) the corporate body has the resources—

(i) to comply with the obligations imposed on a licence holder of a licence of the kind sought by the application; and

(ii) to undertake the activities for which the licence is sought.

(2) In determining whether the corporate body is suitable to hold a licence, the Director-General may consider—

(a) the connections and associations that the corporate body and its directors and employees have with other persons who may have the ability to influence the conduct of the person:

(b) the previous business experience of the directors and employees of the corporate body, and of the shareholders of the corporate body who are presently in a position to influence the management of the corporate body (as applicable):

(c) whether the corporate body is in financial circumstances that may significantly limit the capacity of the corporate body to comply with its obligations under a licence:

(d) the reputation of the directors and employees of the corporate body, having regard to matters going to their character, honesty, and professional and personal integrity:

(e) any other matters the Director-General considers relevant.

(3) In order to ascertain whether an applicant or any person who is a director of the corporate body has a conviction of the kind specified in **subclause (1)(b)**, the Director-General may ask the New Zealand Police to check if any of those persons has a conviction of that kind.

6 Eligibility and suitability of responsible person

(1) An individual is eligible to be a responsible person if the individual—

(a) is authorised by the corporate body concerned to control the activities for which the licence is sought, and to communicate, on behalf of the corporate body, with the Director-General or any person authorised by the Director-General; and

(b) is 18 years or older; and

(c) has not been convicted of—

(i) an offence against this Act or of any other drug-related offence; or

(ii) a crime involving dishonesty as defined in section 2(1) of the Crimes Act 1961; or

(iii) an offence punishable by imprisonment for 2 or more years; or

(iv) an offence outside New Zealand that, if committed in New Zealand, would fall within **subparagraph (i)**, **(ii)**, or **(iii)**; and

(d) has not, at any time, been addicted or habituated to the use of a controlled drug, prescription medicine, or restricted medicine; and

(e) has not, at any time, been declared bankrupt or been a director of a corporate body that has been put into receivership or liquidation; and

(f) has not held a licence under this Part that has been revoked at any time in the 5 years immediately preceding the date of their nomination; and

(g) is familiar with, and has the expertise and the resources to comply with, the obligations imposed on a responsible person of a licence of the kind sought by the application.

(2) In determining whether an individual is a suitable person to be a responsible person, the Director-General may consider—

(a) the connections and associations that the person has with other persons:

(b) the person's reputation, having regard to matters going to their character, honesty, and professional and personal integrity:

(c) any other matters the Director-General considers relevant.

(3) In order to ascertain whether any person nominated as the responsible person has a conviction of the kind specified in **subclause (1)(c)**, the Director-General must ask the New Zealand Police to check if any of those persons has a conviction of that kind.

Safety of location

7 Location specified in application must be safe

(1) A location is safe if it is located at least 1 kilometre away from an area specified by regulations as unsuitable to undertake the activities that are authorised by the licence and—

(a) if the activities are conducted outside a building, at least 5 kilometres away from an area zoned residential: or

(b) if the activities are conducted inside a building, at least 1 kilometre away from an area zoned residential.

(2) Subject to **subclause (1)**, if the location is located in an area zoned industrial, the location is safe only if the activities are conducted inside a building.

(3) The Director-General may inspect a location specified in an application to check if it is safe.

Conditions or restrictions on licences

8 Director-General may impose, vary, or revoke conditions or restrictions

(1) In approving a licence, the Director-General may impose any conditions or restrictions that the Director-General considers, in the circumstances of the particular case, necessary or desirable in addition to the conditions in this Act.

(2) The Director-General may, by notice in writing to the licence holder,—

(a) vary or revoke a condition or restriction imposed under **subclause (1)**; or

(b) impose a new condition or restriction under **subclause (1)**.

Issue and duration of licences

9 Issue and form of licence

(1) As soon as practicable after approving an application under **clause 3**, the Director-General must issue a licence that states the following:

(a) the name of the licence holder:

(b) if the licence is issued to a corporate body, the name of every responsible person:

(c) the activities that are authorised by the licence:

(d) each location where cannabis for medicinal purposes may be (as applicable)—

(i) stored:

(ii) cultivated:

(iii) processed:

(iv) manufactured:

(e) the persons authorised by the licence to engage in activities authorised by the licence:

(f) the period for which the licence is in force:

(g) the standard conditions specified in **Part 2**:

(h) any conditions or restrictions imposed by the Director-General under **clause 8**.

(2) The Director-General must sign and date the licence and give or send it to the licence holder.

10 Duration and extension of licence

(1) A licence is in force for the period stated in the licence.

(2) The stated period must not exceed 5 years.

(3) A licence holder whose licence has been issued for a period of less than 5 years may, before the expiry of the licence, apply to the Director-General for an extension of the period.

(4) If satisfied that the licence holder has complied with the conditions and restrictions of the licence holder's licence, the Director-General may, by notice to the licence holder, extend the period by a further period stated in the notice.

(5) No extension may be granted that would result in a licence being in force for more than 5 years after the date of its issue.

(6) Subject to **subclause (5)**, the Director-General may extend the period of a licence on more than 1 occasion.

(7) **Subclause (1)** is subject to **subclause (4)**.

Part 2
Standard conditions of licences

11 Licence holder to inform people of obligations

A licence holder must inform any person who carries out activities authorised by the licence of—

(a) each condition that is relevant to that person, including each variation or revocation of such a condition; and

(b) any revocation or suspension of the licence under **clause 21**.

12 Activities must be undertaken under control of licence holder

An activity authorised under a licence must only be undertaken if it is undertaken under the control of—

(a) the licence holder, if the licence holder is an individual; or

(b) a responsible person, if the licence holder is a corporate body.

13 Licence holder to deal with cannabis for medicinal purposes responsibly

A licence holder and a responsible person must deal with cannabis for medicinal purposes that is in their possession or control in a way that effectively guards against the risk of misuse for unlawful purposes.

14 Licence holder to employ or engage suitable staff

A licence holder must take all reasonable steps to only employ or engage a person to carry out activities authorised by the licence who—

(a) is aged 18 years or over; and

(b) has not been convicted of—

(i) an offence against this Act or of any other drug-related offences; or

(ii) a crime involving dishonesty within the meaning of the Crimes Act 1961; or

(iii) an offence punishable by imprisonment for 2 or more years; or

(iv) an offence outside New Zealand that, if committed in New Zealand, would fall within **subparagraph (i)**, **(ii)**, or **(iii)**; and

(c) is not addicted or habituated to the use of a controlled drug, prescription medicine, or restricted medicine; and

(d) is not a member of a gang as defined in section 4 of the Prohibition of Gang Insignia in the Government Premises Act 2013.

15 Licence holder to be party to certain contracts

(1) A licence holder of a licence authorising the obtaining or cultivation of cannabis plants for the purposes of producing cannabis for medicinal purposes, but not a licence authorising the processing of cannabis for medicinal purposes, must have a contract with another licence holder of a licence authorising the processing of cannabis for medicinal purposes.

(2) A licence holder of a licence authorising only the processing of cannabis for medicinal purposes must have a contract with another licence holder of a licence authorising the manufacture of cannabis for medicinal purposes.

(3) A contract is not required to be in existence in circumstances prescribed by regulations.

16 Licence holder to undertake activities in specified location

A licence holder must only undertake an activity authorised by a licence in the location specified for the activity in the licence.

17 Licence holder to store cannabis for medicinal purposes securely

A licence holder must store cannabis for medicinal purposes securely.

18 Licence holder to notify the Director-General of certain matters

A licence holder must notify the Director-General as soon as reasonably practicable if—

(a) the licence holder ceases to be eligible under **clause 4(1)** or **5(1)** to be a licence holder:

(b) the licence holder may no longer be a suitable person to be a licence holder under **clause 4(2)** or **5(2)**:

(c) the responsible person may not be eligible or a suitable person to be the responsible person under **clause 6**:

(d) the location specified in the application is not safe in accordance with **clause 7**:

(e) any standard condition in **Part 2** is breached:

(f) any condition or restriction imposed by the Director-General under **clause 8** is breached:

(g) any other matters that may require or permit the Director-General to revoke the licence:

(h) any matter prescribed by regulations.

Part 3
Modification and cancellation of licences

Approval to certain changes

19 Certain changes not to be made without prior approval of Director-General

(1) A licence holder must not change, without the prior approval of the Director-General, any of the following:

(a) the composition of the directors of the corporate body:

(b) the location specified in the licence:

(c) the responsible person.

(2) An approval under this clause must be—

(a) sought at least 30 days before a proposed change is to take effect; and

(b) made in writing to the Director-General and must be accompanied by the licence.

(3) If the Director-General approves a change of the kind described in **subclause (1)(a)** to **(c)**, the Director-General must amend the licence or issue a replacement licence to reflect the approved change.

Surrendering, revocation, or suspension of licence

20 Surrender of licence

A licence holder may, at any time, surrender their licence to the Director-General, in which case the licence expires on the date on which the licence is received by the Director-General.

21 Revocation or suspension of licence

(1) The Director-General may revoke or suspend a licence if—

(a) the licence holder is not eligible under **clause 4(1)** or **5(1)** to be a licence holder:

(b) the licence holder is not a suitable person to be a licence holder under **clause 4(2)** or **5(2)**:

(c) the responsible person is not eligible or a suitable person to be the responsible person under **clause 6**:

(d) the location specified in the application is not safe in accordance with **clause 7**:

(e) any standard condition in **Part 2** is breached:

(f) any condition or restriction imposed by the Director-General under **clause 8** is breached:

(g) the Director-General considers there is any other good reason to revoke or suspend the licence.

(2) Before revoking or suspending the licence, the Director-General must—

(a) notify the licence holder, and the responsible person (as applicable), of the proposal to revoke or suspend the licence; and

(b) give the licence holder, and the responsible person (as applicable), an opportunity to make submissions within a reasonable period on the proposal; and

(c) take into account any submissions received within that period.

(3) **Subclause (2)** does not apply if the Director-General considers that there is good reason not to give notice of the intention to revoke or suspend a licence.

(4) If the Director-General revokes or suspends a licence, the Director-General must notify the licence holder and the responsible person (as applicable) in writing of the revocation or suspension.

22 Record of revocations and suspensions

The Director-General must keep a record of every revocation and suspension of a licence.

Review of Director-General's decisions

23 Review of Director-General's decisions

(1) A licence holder who is dissatisfied with a decision of the Director-General may apply to the Director-General for a review of that decision.

(2) The licence holder must apply not later than 14 days after the day on which the notice of decision is given to the licence holder.

(3) The Director-General must appoint a person to conduct the review (the **reviewer**) and the reviewer may be an employee of the Ministry of Health but must not have had any previous involvement in the case.

(4) If, after conducting the review, the reviewer—

(a) considers the decision was well founded, the reviewer must recommend that the decision be confirmed:

(b) does not consider the decision was well founded, the reviewer must recommend that the decision be cancelled.

(5) After considering the recommendation given by the reviewer, the Director-General must confirm or cancel the decision and give notice to the licence holder.

(6) A notice under **subclause (5)** has effect as soon as it is given to the licence holder.

Part 4
Annual report

24 Annual report

(1) For every period of 12 months in which a licence holder holds a licence, the licence holder must submit an annual report to the Director-General.

(2) The annual report required in **subclause (1)** must—

(a) be in the prescribed form (if any); and

(b) contain the information specified in **clause 25**.

25 Information to be contained in annual report

A licence holder must, in an annual report, provide the following information:

(a) the authorised activities undertaken by the licence holder in that period:

(b) the volume and type of cannabis for medicinal purposes the licence holder is cultivating, processing, or manufacturing:

(c) any other information prescribed by regulations.

Part 5
Medicinal cannabis products

Provisional consent for distribution of new medicinal cannabis products

26 Provisional consent application

A manufacturer of a new medicinal cannabis product may apply to the Minister for provisional consent to sell, distribute, or advertise the new medicinal cannabis product under section 23 of the Medicines Act 1981.

27 Duration of provisional consent

(1) Every provisional consent given for a medicinal cannabis product under section 23 of the Medicines Act 1981 must have effect for 5 years or any shorter period that the Minister may determine.

(2) The Minister may, by notice in the *Gazette*, renew any provisional consent for a period not exceeding 5 years on any 1 occasion.

(3) If, during the period of a provisional consent for any new medicinal cannabis product, the Minister grants a consent under section 20 of the Medicines Act

1981 in respect of the same medicinal cannabis product, the provisional consent is revoked.

(4) This clause overrides sections 23(4) to (4B) of the Medicines Act 1981.

Advertising medicinal cannabis product

28 Restrictions on advertising

(1) Subject to **subclause (2)** and any regulations made under this Act, a holder of a licence under this Act, or any other person, must not publish, or cause or permit to be published any advertisement.

(2) An advertisement of a medicinal cannabis product or new medicinal cannabis product may—

(a) be distributed to medical practitioners, nurse practitioners, or pharmacists; or

(b) be contained in a publication that circulates solely or mainly or is distributed solely or mainly to medical practitioners, nurse practitioners, or pharmacists.

(3) An advertisement under **subclause (2)** must—

(a) state the name and address of the place of business of the person by whom or at whose request the advertisement is published; and

(b) contain a conspicuous statement sufficient to indicate that the advertisement relates to a medicinal cannabis product, or, if the advertisement is comprised in a price list or similar publication, contains the abbreviation "MCP"; and

(c) contain any other information prescribed by regulations made under this Act.

(4) In this section,

advertisement—

(a) means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of a controlled drug (for example, a sign, publication, or leaflet), and includes any trade circular, any label, and any advertisement in a trade journal; and

(b) includes any matter referred to in **paragraph (a)** that is represented in an electronic or a digital medium.

Part 6
Offences

29 Offence to breach conditions or restrictions

(1) Every person commits an offence who, being a licence holder or a responsible person under a licence, breaches a condition or restriction of the licence imposed by or under this Act or by the Director-General.

(2) A person who commits an offence under **subclause (1)** is liable on conviction to a term of imprisonment not exceeding 3 months or a fine not exceeding $500,000.

30 Offence to fail to submit an annual report

(1) Every person commits an offence who, being the licence holder of a licence, fails to submit an annual report to the Director-General as required by **clause 24(1)**.

(2) A person who commits an offence under **subclause (1)** is liable on conviction to a term of imprisonment not exceeding 3 months or a fine not exceeding $500,000.

31 Offence to contravene advertising restrictions

A person who contravenes **clause 28(1)** commits an offence and is liable on conviction to a fine not exceeding $500,000.

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