House of Representatives

Supplementary Order Paper

Tuesday, 4 December 2018

Misuse of Drugs (Medicinal Cannabis) Amendment Bill

Proposed amendments to SOP No 177

Dr Shane Reti, in Committee, to move the following amendments:

Clause 2

Replace clause 2 (page 2) with:

- 2 Commencement
- (1) **Sections 7, 8AA, and 9A** come into force on the day that is 6 months after the date on which the Act receives the Royal assent.
- (2) The rest of this Act comes into force on the day after the date on which it receives the Royal assent.

Clause 4

In *clause 4(1)* (page 2), insert in its appropriate alphabetical order:

cannabis for medicinal purposes has the meaning given in clause 1 of Schedule 6

Clause 7

Replace the deleted *clause* 7 (page 4) with:

- 7 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 6** applies to any licences to cultivate, process, or manufacture cannabis for medicinal purposes.

New clause 8AA

After clause 8 (page 5), insert:

8AA Section 37 amended (Regulations)

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

- (ca) prescribing any form of medicinal cannabis product under clause 1 of Schedule 6:
- (cb) prescribing an area that is unsuitable under clause 8 of Schedule 6:
- (cc) prescribing the form for the annual report to be submitted, and additional information to be provided, to the Director-General under clauses 25 and 26 of Schedule 6:

New clause 9A

After clause 9 (page 6), insert:

9A New Schedule 6 inserted

After Schedule 5, insert the **Schedule 6** as set out in the **Schedule** of this Act.

New Schedule

After clause 10 (page 7), insert:

Schedule New Schedule 6 inserted

Schedule 6

Schedule 6

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1	Inter	pretation of this Schedule		
	In this	In this Schedule, unless the context otherwise requires,—		
	(exclu	abis means the flowering or fruiting tops of a cannab ading the seeds and leaves when not accompanied by the which the resin has not been extract by whatever name mated	he tops)	
	a canı ted, p	abis for medicinal purposes means cannabis, cannab nabis plant, or any cannabis preparation that is grown, processed, or manufactured for the purpose of producinal cannabis product	cultiva-	
	canna	abis plant means—		
	(a)	any plant of the genus Cannabis:		
	(b)	any part of a plant of the genus <i>Cannabis</i> including, limited to, the seeds, stems, or leaves of the plant	but not	
		abis resin means the separate resin, whether crude or pred from the cannabis plant	ourified,	
	corpo	orate 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 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 product means—

- (a) a finished product of cannabis for medicinal purposes; and
- (b) is a medicine under section 3(1) of the Medicines Act 1981; and
- (c) is—
 - (i) a liquid, including, but not limited to oil:
 - (ii) a pill:
 - (iii) a vaporised delivery method:
 - (iv) in any other form prescribed by regulations; but
- (d) does not include—
 - (i) any unprocessed or non-standardised cannabis or cannabis resin:
 - (ii) any unprocessed or non-standardised cannabis plant:
 - (iii) any unprocessed or non-standardised cannabis preparation:
 - (iv) any product that must be smoked.

smoke has the same meaning given in section 96A of the Civil Aviation Act 1990.

Part 2 Application and eligibility for licences

Application for licence

- 2 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.

3 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 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 an licence

4 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 5(1)** or **6(1)** to hold the licence sought; and
 - (b) the applicant is a suitable person under **clause 5(2)** or **6(2)** to hold the licence sought; and

- (c) the individual named in the application is eligible under **clause 7(1)** and is a suitable person under **clause 7(2)** to be the responsible person; and
- (d) the location specified in the application is safe in accordance with **clause 8**; and
- the applicant will comply with the standard conditions in Part 3 and any other conditions or restrictions that may be imposed under clause 9; 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 to 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 10**.

Eligibility for licence

5 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—
 - 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 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 his or her 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.
- 6 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 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
- every director of the corporate body has not, at any time, (d) been declared bankrupt or been a director of a corporate body that has been put into receivership or liquidation; and
- no licence held by the corporate body or to a director of the (e) 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
- the corporate body has nominated 1 or more individuals to be (g) responsible persons, being individuals who are eligible under clause 7; 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
 - to undertake the activities for which the licence is (ii) sought; and
- (i) the corporate body has the resources
 - 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
 - the connections and associations that the corporate body and (a) its directors and employees have with other persons who may have the ability to influence the conduct of the corporate body or its directors and employees:
 - (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):
 - whether the corporate body is in financial circumstances that (c) 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.

7 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—
 - 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 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 **paragraph (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 who may have the ability to influence the conduct of the person:
 - (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

8 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

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

- 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 **sub- clause (1)**; or

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

Issue and duration of licences

10 Issue and form of licence

- (1) As soon as practicable after approving an application under clause 4, 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 3**:
 - (h) any conditions or restrictions imposed by the Director-General under **clause 9**.
- (2) The Director-General must sign and date the licence and give or send it to the licence holder.

11 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 3

Standard conditions of licences

12 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 22.

13 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.

14 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.

15 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.

16 Licence holder to be party to certain contracts

- (1) A licence holder of a licence authorising obtaining or cultivating cannabis 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.

17 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.

18 Licence holder to store cannabis for medicinal purposes securely

A licence holder must store cannabis for medicinal purposes securely.

19 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 5(1)** or **6(1)** to be a licence holder:
- (b) the licence holder may no longer be a suitable person to be a licence holder under **clause 5(2)** or **6(2)**:
- (c) the responsible person may no longer be eligible or a suitable person to be the responsible person under **clause 7**:
- (d) the location specified in the application is not safe in accordance with **clause 8**:
- (e) any standard condition in **clauses 12** to **18** is breached:

- (f) any condition or restriction imposed by the Director-General under **clause 9** is breached:
- (g) any other matters that may require or permit the Director-General to revoke the licence.

Part 4

Modification and cancellation of licences

Approval to certain changes

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

21 Surrender licence

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

22 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 5(1) or 6(1) to be a licence holder:
 - (b) the licence holder is not a suitable person to be a licence holder under clause 5(2) or 6(2):

- (c) the responsible person is not eligible or a suitable person to be the responsible person under **clause 7**:
- (d) the location specified in the application is not safe in accordance with **clause 8**:
- (e) any standard condition in **Part 3** is breached:
- (f) any condition or restriction imposed by the Director-General under **clause 9** 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 license holder and the responsible person (as applicable) in writing of the revocation or suspension.

23 Record of revocations and suspension

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

Review of Director-General's decisions

24 Review of Director-General's decisions

- 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
 - considers the decision was well founded, the reviewer must recommend that the decision be confirmed:
 - does not consider the decision was well founded, the (b) 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.
- A notice under **subclause** (5) has effect as soon as it is given to (6) the licence holder.

Part 5 **Annual report**

25 **Annual report**

- For every period of 12 months in which a licence holder holds a (1) licence, the licence holder must provide an annual report to the Director-General.
- (2) The annual report required in **subclause (1)** must
 - be in the prescribed form (if any); and (a)
 - (b) contain the information specified in clause 26.

26 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:
- the volume and type of cannabis for medicinal purposes the (b) licence holder is cultivating, processing, or manufacturing:
- (c) any other information prescribed by regulations.

Part 6 **Offences**

Offence to breach conditions or restrictions 27

(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.
- 28 Offence for failing to provide 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 25(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.

Explanatory note

This Supplementary Order Paper inserts a new Schedule 6 to provide for a medicinal cannabis scheme that will licence domestic medicinal cannabis production. The new Schedule 6 provides as follows:

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

Wellington, New Zealand: