

## **EXPLANATORY STATEMENT**

Minute No. \_\_\_\_\_ of 2019 - Minister for Health

Subject - *Narcotic Drugs Act 1967*

*Narcotic Drugs Amendment (Review Recommendations) Regulations 2019*

The *Narcotic Drugs Act 1967* (the Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs, 1961, as in force from time to time. The Convention, as amended by the 1972 Protocol, is set out in Schedule 1 to the Act.

The Act was amended in 2016 to establish a licensing and permit scheme to regulate the cultivation of cannabis plants and the production of cannabis and cannabis resin. Cultivation and production, and related activities, under the scheme are for medicinal purposes or for research relating to medicinal cannabis. The Act includes a separate licensing and permit scheme to regulate the manufacture of drugs covered by the Convention, relevantly including cannabis, cannabis resin and extracts and tinctures of cannabis.

Section 27(1) of the Act provides that the Governor-General may make regulations prescribing matters:

- (a) required or permitted by this Act to be prescribed by the regulations; or
- (b) necessary or convenient to be prescribed for carrying out of giving effect to this Act.

The *Narcotic Drugs Regulation 2016* (the Principal Regulation) prescribes various matters required or permitted by the Act to be prescribed by the regulations for the purposes of the medicinal cannabis scheme in the Act.

Section 26A of the Act requires that the Minister cause a review of the operation of the Act to be undertaken as soon as possible after the second anniversary of the 2016 amendments establishing the medicinal cannabis scheme, with a written report tabled in each House of Parliament before the third anniversary of those amendments (ie, by 29 October 2019). The Minister for Health appointed Professor John McMillan AO to conduct the review for the purposes of s 26A (the Review) and the report was tabled in Parliament on 5 September 2019.

The purpose of the Regulations is to amend the Principal Regulation to implement certain of the Review's recommendations. The Regulations make minor amendments to the Principal Regulation to avoid unnecessary duplication, simplify certain obligations relating to the licence and permit application processes and clarify and better align terminology with the Act.

Other recommendations requiring amendments to the Act and further amendments to the Principal Regulation are proposed to be made at a later stage.

Details of the Regulations are set out in the [Attachment](#).

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on 1 January 2020.

### **Consultation**

As documented in the report of the Review, consultation with stakeholders was a key part of that Review. That consultation process included publication of a discussion paper on which 25 written submissions were received; holding, before publication of the discussion paper, three public meetings in Brisbane, Sydney and Melbourne; consultation, at three of its meetings, with the Australian Advisory Council on the Medicinal use of Cannabis; the Medicinal Cannabis Access Working Group; the Cultivation and Production Working Group and the Law Enforcement Working Group; the Medicinal Cannabis Industry Association; the Medicinal Cannabis Council Inc and consultation with Queensland and Victorian Government public health officials and law enforcement officers from Western Australia.

Authority: Subsection 27(1) of the  
*Narcotic Drugs Act 1967*

**Details of the Narcotic Drugs Amendment (Review Recommendations) Regulations 2019**

**Section 1 - Name of Regulations**

This section provides that the title of the Regulations is the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019*.

**Section 2 - Commencement**

This section provides for the Regulations to commence on 1 January 2020.

**Section 3 - Authority**

This section provides that the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* is made under the *Narcotic Drugs Act 1967*.

**Section 4 - Schedules**

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

**Schedule 1 - Amendments**

**Item [1] - section 4 (definition of *affected by bankruptcy*)**

Consequential on the repeal of paragraph 5(3)(j), the definition of ‘affected by bankruptcy’ in section 4 of the Principal Regulations no longer has work to do and is therefore repealed.

**Item [2] – paragraph 4A(b)**

Section 4A of the Principal Regulation prescribes certain substances for the purposes of paragraph (a) of the definition of ‘drug’ in subsection 4(1) of the Act.

Paragraph 4A(b) of the Principal Regulation prescribes ‘cannabidiol (including all isomers and salts)’ for the purposes of paragraph (a) of the definition of ‘drug’ in subsection 4(1) of the Act. The amendment excludes cannabidiol (including all isomers and salts) from being prescribed under section 4A of the Principal Regulation as a drug for the purpose of the Act.

Section 4A is intended to specify particular cannabis related drugs for which Australia has international obligations to control. Although paragraph 4A(b) presently lists cannabidiol as one of those drugs, cannabidiol is not a narcotic and does not, therefore, appear in the schedules of either of the two major drug treaties that provide those international controls, the *Single Convention on Narcotic Drugs, 1961* (the Single Convention) or the *Convention on Psychotropic Substances, 1971*, to which Australia is a party.

The Act already adequately controls extracts of cannabis which would normally include substances (resins for example) containing both tetrahydrocannabinol (THC) and cannabidiol. There is no need for an additional control on the pure chemical cannabidiol

itself, and indeed doing so negatively impacts industry as it impedes the development of synthetic cannabinoid medicines.

The repeal of ‘cannabidiol’ from prescription as a drug is also consistent with the November 2018 recommendation of the World Health Organisation Expert Committee on Drug Dependence (at its 41<sup>st</sup> meeting) communicated to the Secretary General of the United Nations that preparations considered to be pure cannabidiol should not be scheduled within the International Drug Control Conventions by adding a footnote to the entry for cannabis and cannabis resin in Schedule 1 of the Single Convention on Narcotic Drugs 1961 to read: *Preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9THC are not under international control.*

### **Item [3] – paragraphs 5(2)(h), (i), (j), (k), (l), (m) and (n)**

#### *Paragraph 5(2)(h)*

Consistent with the notation of the Report on the Review of the *Narcotic Drugs Act 1967* (in a discussion forming the basis of recommendation 8) paragraph 5(2)(h) of the Principal Regulation repealed and substituted with minor amendments. This ensures greater consistency with paragraph 8G(1)(d) of the Act. That provision of the Act requires that the Secretary must refuse to grant a medicinal cannabis licence if the Secretary is not satisfied on reasonable grounds that the applicant will take all reasonable measures to ensure the physical security of cannabis plants, cannabis or cannabis resin: (i) in the applicant’s possession or control; and (ii) obtained, cultivated or produced under, or purportedly under, the licence. The Report on the Review noted that this general licensing requirement could be supplemented by instructions issued by the Secretary, guidelines issued by the Minister or information guidance issued by the Department.

#### *Paragraphs 5(2)(i) to (l)*

Paragraphs 5(2)(i), (j), (k) and (l) of the Principal Regulation require the applicant to, with its application, provide details of certain arrangements that will be in place on various matters that broadly speaking relate to the physical security of cannabis and cannabis resin. However, as the Report on the Review of the *Narcotic Drugs Act 1967* noted (in a discussion forming the basis of recommendation 8 of the Review) information about these matters is already within the scope of the information required under paragraph 5(2)(h) as amended. Paragraphs 5(2)(i), (j), (k) and (l) is therefore repealed.

#### *Paragraphs 5(2)(m) and (n)*

The information requirements prescribed by existing paragraphs 5(2)(m) and (n) reflect, on the basis of the operation of sections 8J and 10J of the Act, an assumption that the holder of a medicinal cannabis licence authorising cultivation and/or production must (relevantly) have a contract for supply of (relevantly) cannabis plants, cannabis or cannabis resin, with the holder of another medicinal cannabis licence.

Among other things, the assumption takes no account of the possibility that the Secretary may exercise his or her discretion to determine that such a contract is not required to be in existence in the case of a medicinal cannabis licence authorising production (see paragraph 10J(3)(b) of the Act). The assumption may inadvertently stifle innovation by industry, such as in relation to the export of cannabis plants for the purposes of their genetics. It remains, however, relevant to the Secretary’s consideration of an application for a medicinal cannabis licence to be informed of the applicant’s arrangements for supply of cannabis plants, cannabis or cannabis resin to a recipient. Each of paragraphs 5(2)(m) and (n) is therefore

repealed and substituted with a new paragraph 5(2)(m) providing for this more streamlined information.

**Item [4] – Paragraphs 5(3)(i), (j) and (k) and (4)(i) and (j)**

Paragraphs 5(3)(i), (j) and (k) and (4)(i) and (j) are repealed.

Paragraph 5(3)(i) is repealed on the basis that the prescribed information (details of any relevant disciplinary or other action for an applicant holding professional qualifications regulated by law) is sufficiently provided for by another (more broadly expressed) provision of the Principal Regulation; paragraph 5(3)(l) requires an application to include information on the details of any matters affecting whether the applicant is of good repute, being matters going to the applicant's character, honesty and professional and personal integrity.

For reasons similar to those in support of the repeal of paragraph 5(3)(i) paragraph 5(4)(i), applying to a body corporate (not an individual) is repealed.

Paragraph 5(3)(j), requiring an application include 'whether the applicant is affected by bankruptcy' was identified in the Final Report on the Review of the *Narcotic Drugs Act 1967* as an example of a provision with inexact and demanding decision making criteria. Further; paragraph 5(3) (l) of the Principal Regulation already requires the application include whether there are matters which may affect the person being of good repute and paragraph 6(2)(b) requires an application is accompanied by documents demonstrating the matters which the Secretary may, by s 8A(g) of the Act, take into account when considering whether the applicant is a fit and proper person; that is documents that provide evidence that the applicant has a sound and stable financial background and is not in financial circumstances that may significantly limit the applicant's capacity to comply with the applicant's obligations under the licence. Paragraph 5(3)(j) is therefore repealed.

Paragraph 5(3)(k), requiring the application include 'details of the applicant's current financial circumstances', was identified in the Final Report on the Review of the *Narcotic Drugs Act 1967* as an example of an obligation with inexact and demanding decision making criteria. The comments made in relation to the repeal of paragraph 5(3)(j) noting the existence of paragraph 5(3)(l) and 6(2)(b) also apply in relation to the repeal of paragraph 5(3)(k).

Similar reasons, including the existence of paragraph 5(4)(k), support, for an application from a body corporate, the repeal of paragraph 5(4)(j).

**Item [5] – Subsections 5(5), (6) and (7)**

Item 5 repeals subsections 5(5), (6) and (7) (not including the note).

*Subsection 5(5)*

Subsection 5(5) requires an application contains details of the arrangements that will be in place to record various matters as set out in the relevant paragraphs. The Final Report on the Review of the *Narcotic Drugs Act 1967* noted that this was unnecessarily prescriptive. Subsection 5(5) is therefore repealed; a substantive record-keeping obligation can be imposed as a condition by the Secretary at the time a licence is granted, the breach of which is a compliance matter.

### *Subsection 5(6)*

It is a statutory condition on a cannabis licence, under section 10F of the Act, that the licence holder employ or engage suitable staff and subsection 10F(1) sets out certain disqualifying criteria for this purpose.

Subsection 5(6) of the Principal Regulation which requires an application contain details of the procedures (including recruitment procedures) that will be used by the applicant to ensure compliance with subsection 10F(1) of the Act was identified in the Final Report on the Review of the *Narcotic Drugs Act 1967* as an example of a provision with inexact and demanding decision making criteria. Subsection 5(6) is repealed on the basis that it is not necessary for the Secretary to know the details of the recruitment or other procedures that an applicant will utilise to ensure compliance with the statutory condition in section 10F of the Act.

### *Subsection 5(7)*

Subsection 5(7) requires an application for a licence to include details of various security arrangements relating to the prevention of unauthorised access, including in relation to the arrangements that will be in place to control the activities and movement of certain persons, and relating to the equipment used to monitor, detect and record unauthorised access.

The subsection is considered unnecessary and duplicative as the substantive obligation for an application to sufficiently detail the security arrangements in place are included under paragraph 5(2)(h) of the Principal Regulation (as amended). It will be a matter for a licence applicant to provide enough information under that paragraph to convince the Secretary (or delegate) that the proposed security arrangements are sufficient. Accordingly, subsection 5(7) is repealed.

### **Item [6] – Section 7A**

Section 7A, which provides general grounds for the refusal of an application for a medicinal cannabis licence, be repealed and, to clarify its operation, a revised text substituted.

The substituted provision gives clearer effect to the policy than the existing section 7A (see the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*); it clarifies that for the purposes of paragraph 8G(1)(f) of the Act, a circumstance in which a licence must not be granted is that the applicant for the licence is reasonably likely: (a) not to be a resident of Australia; and (b) not to carry on business in Australia at a time when the licence is proposed to be in force. It is important that the obligations imposed on licence holders are enforceable against a licence holder who, in very broad terms, has a presence in Australia.

The circumstances are framed to relate to the period for which the licence is proposed to be in force (and not necessarily the time the application is made, or being considered), in order to maximise the scope for innovation in the application of the amended provision.

### **Items [7] and [8] – Section 7B**

Items [7] and [8] amend section 7B of the Principal Regulation to repeal paragraphs 7B(a), (b) and (c).

As amended, section 7B continues to ensure a licensee under the Act may only supply to a person who holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989*, generally also known as a good manufacturing practice (GMP) licence. The repeal of paragraphs 7B(a), (b) and (c) recognises the difficulty in ensuring, under operation of the Act and Principal

Regulation, that the GMP licence holder to whom the medicinal cannabis holder supplies product will itself only supply in the prescribed circumstances set out in those paragraphs. Adequate provision is provided for the risk of diversion or control over the proposed supply pathway by the requirement that supply is to a GMP licence holder.

**Items [9], [10] and [11] – Paragraphs 8(3)(a), (b) and (c)**

For greater consistency with the Single Convention item 9 amends paragraph 8(3)(a) of the Principal Regulation to repeal references to ‘strains’.

For consistency with the repeal in section 4A of ‘cannabidiol’ from prescription as a drug, item 10 amends paragraph 8(3)(b) to repeal the reference to ‘cannabidiol’; existing paragraph 8(3)(c) is therefore otiose and it is therefore repealed by item 11.

**Item [12] – Subsection 9(2)**

Section 9 of the Principal Regulation sets out the documents that must accompany an application by the holder of a medicinal cannabis licence for a medicinal cannabis permit.

Paragraph 9(2)(b) requires provision of certain evidence relating to cannabis plants the applicant proposes to cultivate. This paragraph duplicates the information an applicant is required to provide under section 8 of the Principal Regulation and paragraph 9(2)(b) and the note are therefore repealed.

**Items [13], [14] and [15] – Subsections 11(2), 11(3) and 11(5)**

Section 11 of the Principal Regulation is in analogous terms to section 5 and is therefore amended consistently with the amendments to section 5 above.

**Item [16] – Section 13A**

Section 13A provides general grounds for refusal of an application for a cannabis research licence. The section is repealed and substituted with a provision in analogous terms to section 7A (as amended), for the same reasons discussed above in relation to section 7A.

**Items [17] - [20] – Subparagraph 14(2)(d)(iv) and paragraphs 14(3)(a) and (b)**

These items make minor amendments to the relevant provisions to omit references to cannabidiol and other cannabinoids, consistently with the amendments to section 4A and subsection 8(3).

**Item [21] – Section 15**

Section 15 of the Principal Regulation provides for the document requirements for an application for a cannabis research permit and is analogous to existing paragraph 9(2)(b). For consistency with the repeal of paragraph 9(2)(b), section 15 is also repealed in full.

**Item [22] – Paragraph 17(1)(a)**

This item makes a minor amendment to paragraph 17(1)(a) to substitute ‘medicinal cannabis’ for the reference to ‘particular types or strains of cannabis plants’, for consistency with the amendment above to subsection 8(3) of the Principal Regulation.

**Item [23] – Subsections 19(1) and (2)**

Section 19 of the Principal Regulation prescribes the matters that must be dealt with in a contract mentioned in subsection 10J(1) of the Act. This item repeals and substitutes subsections 19(1) and (2) of the Principal Regulation to simplify the matters that, in effect, constitute mandatory contract requirements, so that they are limited to focussing on tetrahydrocannabinol (THC) levels and numbers of cannabis plants to be supplied/quantity

of cannabis or cannabis resin to be supplied (as relevant to the cultivation/production licence).

**Item [24] and [25] – Subsection 19(10)**

Subsections 19(9) and (10) of the Principal Regulation provide for the circumstances in which a contract referred to in subsection 10J(2) of the Act is not required to be in existence.

Subsection 19(10) is in analogous terms to existing paragraphs 7B(a), (b) and (c) of the Principal Regulation and is amended for consistency with the amendments to section 7B above.

**Item [26]-[27] – Section 34**

Section 34 of the Principal Regulation provides for a licence holder to surrender a cannabis licence or permit by giving written notice in accordance with that section. The notice must, among other things, contain the day on which the surrender is proposed to take effect, being a day that is not less than 20 business days after the day the notice is given to the Secretary. This minimum notice period is intended to provide sufficient time for any authorised activities to cease and for any cannabis plants, cannabis or cannabis resin to be dealt with appropriately, before the licence or permit ceases to have effect.

The section is amended so that the default position is that a licence or permit ceases to be in force 20 business days after the holder gives the Secretary the notice or surrender, or such other (shorter or longer) time period as specified in writing by the Secretary.

**Items [28], [29] and [30] – Section 35**

Section 35 of the Principal Regulation is in analogous terms to existing section 5 and is therefore amended consistently with the amendments to section 5 above.

**Item [31] – Section 36A**

Section 36A of the Principal Regulation is in analogous terms to existing section 7A and is therefore amended consistently with the amendments to section 7A above.

**Items [32] and [33] – Subsection 37(c)**

Subsection 37(c) of the Principal Regulation is in analogous terms to existing paragraphs 7B(a), (b) and (c) and is therefore amended consistently with the amendments to section 7B above.

**Item [34]-[35] – Section 51**

Section 51 of the Principal Regulation is in analogous terms to existing section 34 and is therefore amended consistently with the amendments to section 34 above.

**Item [36] – Insert new provision in Part 6**

This item amends Part 6 of the Principal Regulation to insert new section 58 relating to the application of provisions of the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019*.



## **Statement of Compatibility with Human Rights**

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

### ***Narcotic Drugs Amendment (Review Recommendations) Regulations 2019***

The *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* (the Amendment Regulations) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### **Overview of the Legislative Instrument**

The Amendment Regulations are made under subsection 27(1) of the *Narcotic Drugs Act 1967*. The Amendment Regulations amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation).

The purpose of the Amendment Regulations is to amend the Principal Regulation to implement certain of the Review's recommendations. The Amendment Regulations make minor amendments to the Principal Regulation to avoid unnecessary duplication, simplify certain obligations relating to the licence and permit application processes and clarify and better align terminology with the Act.

### **Human rights implications**

The Amendment Regulations engage, or have the potential to engage, the human right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESR).

#### Article 12 of the ICESR

The right to health is fundamental to the exercise of other human rights. It is a right to enjoy the highest attainable standard of physical and mental health.

The Amendment Regulations engage the human right to health under Article 12 of the ICESR by streamlining the processes for application for licences to cultivate, produce or manufacture medicinal cannabis under the Act thereby reducing regulatory burden for those engaged or proposing to engage in cultivating, producing or manufacturing medicinal cannabis. The anticipated downstream effect is facilitation of less costly access to good quality medicinal cannabis products by Australian patients.

### **Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health.

**Greg Hunt, Minister for Health**