



## **Narcotic Drugs Amendment (Cannabis) Regulations 2018**

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I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 08 February 2018

Peter Cosgrove  
Governor-General

By His Excellency's Command

Greg Hunt  
Minister for Health

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## 1 Name

This instrument is the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

<b>Commencement information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
1. The whole of this instrument	The day after this instrument is registered.	14 February 2018

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under the *Narcotic Drugs Act 1967*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

### *Narcotic Drugs Regulation 2016*

#### **1 At the end of Part 1**

Add:

#### **4A Prescription of substances**

For the purposes of paragraph (a) of the definition of *drug* in subsection 4(1) of the Act, the following substances are prescribed:

- (a) tetrahydrocannabinol (including all isomers, salts and acids);
- (b) cannabidiol (including all isomers and salts);
- (c) dronabinol.

#### **2 Paragraph 5(3)(d)**

After “other persons”, insert “(each of whom is a *connected person*)”.

#### **3 Paragraph 5(3)(e)**

Omit “person mentioned in paragraph (d) with whom the applicant is connected or associated”, substitute “connected person who is a natural person”.

#### **4 After paragraph 5(3)(e)**

Insert:

- (ea) the following details in relation to each connected person that is a body corporate:
  - (i) the name of the body corporate;
  - (ii) the body corporate’s ACN (if any);
  - (iii) the body corporate’s ABN (if any);
  - (iv) the body corporate’s ARBN (if any);
  - (v) the length of the connection or association with the body corporate;
  - (vi) the nature of the connection or association;

#### **5 Paragraph 5(3)(f)**

After “of each”, insert “natural”.

#### **6 Paragraph 5(3)(f)**

Omit “his or her own right or on someone else’s behalf”, substitute “the natural person’s own right or on behalf of another person”.

#### **7 After paragraph 5(3)(f)**

Insert:

- (fa) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate’s own right or on behalf of another person):
  - (i) in relation to the applicant’s business that will undertake the activities;or

- 
- (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

### **8 Paragraph 5(3)(m)**

Omit "Act;"; substitute "Act."

### **9 Paragraph 5(3)(n)**

Repeal the paragraph.

### **10 Paragraph 5(4)(f)**

After "other persons", insert "(each of whom is a *connected person*)".

### **11 Paragraph 5(4)(g)**

Omit "person mentioned in paragraph (f) with whom the body corporate, its directors or officers are connected or associated", substitute "connected person who is a natural person".

### **12 After paragraph 5(4)(g)**

Insert:

- (ga) the following details in relation to each connected person that is a body corporate:
  - (i) the name of that body corporate;
  - (ii) that body corporate's ACN (if any);
  - (iii) that body corporate's ABN (if any);
  - (iv) that body corporate's ARBN (if any);
  - (v) the length of the connection or association with that body corporate;
  - (vi) the nature of the connection or association;
- (gb) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):
  - (i) in relation to the applicant's business that will undertake the activities;  
or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;
- (gc) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):
  - (i) in relation to the applicant's business that will undertake the activities;  
or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;
- (gd) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:
  - (i) the name and date of birth of the person;
  - (ii) the position in the business held by the person;

### 13 After section 7

Insert:

#### 7A Application for medicinal cannabis licence—general grounds for refusal of licence

For the purposes of paragraph 8G(1)(f) of the Act, a circumstance in which a licence must not be granted is if neither of the following apply:

- (a) the applicant for the licence will be carrying out the cultivation of cannabis plants referred to in paragraph 8E(1)(a) of the Act or the production of cannabis or cannabis resin referred to in paragraph 8E(1)(b) of the Act;
- (b) one or more persons, under the direct supervision of the applicant for the licence, will be carrying out that cultivation or production.

#### 7B Application for medicinal cannabis licence—particular grounds for refusal of licence

For the purposes of paragraph 8J(2)(c) of the Act, a purpose is the supply of the cannabis or cannabis resin to a person who holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person in the manufacture of a medicine (within the meaning of that Act), where one or more of the following apply:

- (a) that medicine is to be supplied by a pharmacist in a public hospital in accordance with the *Therapeutic Goods Act 1989*;
- (b) that medicine is to be supplied in circumstances mentioned in subparagraph 11K(2)(b)(i) or (ii) of the Act;
- (c) that medicine is to be supplied by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*.

### 14 After paragraph 11(2)(i)

Insert:

- (ia) if the application is for a licence that will authorise the supply of cannabis plants as mentioned in subparagraph 9D(1)(c)(ia) of the Act—details of that supply;

### 15 Paragraph 11(3)(d)

After “other persons”, insert “(each of whom is a *connected person*)”.

### 16 Paragraph 11(3)(e)

Omit “person mentioned in paragraph (d) with whom the applicant is connected or associated”, substitute “connected person who is a natural person”.

### 17 After paragraph 11(3)(e)

Insert:

- (ea) the following details in relation to each connected person that is a body corporate:
  - (i) the name of the body corporate;
  - (ii) the body corporate’s ACN (if any);
  - (iii) the body corporate’s ABN (if any);



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- (iv) the body corporate's ARBN (if any);
  - (v) the length of the connection or association with the body corporate;
  - (vi) the nature of the connection or association;

**18 Paragraph 11(3)(f)**

After "of each", insert "natural".

**19 Paragraph 11(3)(f)**

Omit "his or her own right or on someone else's behalf", substitute "the natural person's own right or on behalf of another person".

**20 After paragraph 11(3)(f)**

Insert:

- (fa) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):
  - (i) in relation to the applicant's business that will undertake the activities;  
or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;

**21 Paragraph 11(3)(m)**

Omit "Act;", substitute "Act.".

**22 Paragraph 11(3)(n)**

Repeal the paragraph.

**23 Paragraph 11(4)(f)**

After "other persons", insert "(each of whom is a *connected person*)".

**24 Paragraph 11(4)(g)**

Omit "person mentioned in paragraph (f) with whom the body corporate, its directors or officers are connected or associated", substitute "connected person who is a natural person".

**25 After paragraph 11(4)(g)**

Insert:

- (ga) the following details in relation to each connected person that is a body corporate:
  - (i) the name of that body corporate;
  - (ii) that body corporate's ACN (if any);
  - (iii) that body corporate's ABN (if any);
  - (iv) that body corporate's ARBN (if any);
  - (v) the length of the connection or association with that body corporate;
  - (vi) the nature of the connection or association;
- (gb) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person's own right or on behalf of another person):

- (i) in relation to the applicant's business that will undertake the activities;  
or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;
- (gc) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate's own right or on behalf of another person):
- (i) in relation to the applicant's business that will undertake the activities;  
or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant's current income;
- (gd) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else's behalf) in relation to the applicant's business that will undertake the activities:
- (i) the name and date of birth of the person;
  - (ii) the position in the business held by the person;

## 26 After section 13

Insert:

### 13A Application for cannabis research licence—general grounds for refusal of licence

For the purposes of paragraph 9F(1)(f) of the Act, a circumstance in which a licence must not be granted is if neither of the following apply:

- (a) the applicant for the licence will be carrying out the cultivation of cannabis plants referred to in paragraph 9D(1)(a) of the Act or the production of cannabis or cannabis resin referred to in paragraph 9D(1)(b) of the Act;
- (b) one or more persons, under the direct supervision of the applicant for the licence, will be carrying out that cultivation or production.

## 27 At the end of subsection 14(2)

Add:

- ; (d) if one of those activities is an activity covered by subparagraph 9D(1)(c)(ia) of the Act—the following information:
  - (i) the name and address of the holder of the medicinal cannabis licence or the holder of the other cannabis research licence;
  - (ii) the number of cannabis plants that are proposed to be supplied to that holder;
  - (iii) the dates on which those cannabis plants are proposed to be supplied to that holder;
  - (iv) the range of concentration of tetrahydrocannabinol, cannabidiol and other cannabinoids that are likely to be contained in those cannabis plants.

## 28 Subsection 15(2)

Repeal the subsection, substitute:

- 
- (2) If the applicant proposes to cultivate cannabis plants in accordance with the permit, the documents that must accompany the application are documents containing evidence of the following:
- (a) the types and strains of cannabis plants proposed to be cultivated;
  - (b) the range of concentration of tetrahydrocannabinol, cannabidiol and other cannabinoids that are likely to be contained in the cannabis plants proposed to be cultivated.

Note: The document could be a certificate issued by a government authority, a government accredited laboratory or the supplier of the cannabis plants.

## **29 At the end of section 19**

Add:

- (9) For the purposes of paragraph 10J(3)(a) of the Act, the circumstances referred to in subsection (10) of this section are prescribed as circumstances in which a contract referred to in subsection 10J(2) of the Act is not required to be in existence.
- (10) For the purposes of subsection (9), the circumstances are that the production of the cannabis or cannabis resin is for the supply of the cannabis or cannabis resin to a person who holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person in the manufacture of a medicine (within the meaning of that Act), where one or more of the following apply:
- (a) that medicine is to be supplied by a pharmacist in a public hospital in accordance with the *Therapeutic Goods Act 1989*;
  - (b) that medicine is to be supplied in circumstances mentioned in subparagraph 11K(2)(b)(i) or (ii) of the Act;
  - (c) that medicine is to be supplied by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*.

## **30 Section 20**

Before “For the”, insert “(1)”.

## **31 Section 20**

Omit “paragraph 10K(d)”, substitute “paragraph 10K(1)(d)”.

## **32 At the end of section 20**

Add:

- (2) For the purposes of paragraph 10K(2)(a) of the Act, the period for a matter covered by paragraph (1)(a), (b), (c), (d), (e) or (f) of this section is 72 hours starting when the matter comes to the attention of the licence holder.

## **33 At the end of section 28**

Add:

- (6) If this section requires a notice to be given to a licence holder stating the reasons for a proposed suspension, the Secretary:
- (a) must not disclose information identified as sensitive law enforcement information under subsection 14LA(1) or (2) of the Act in the notice; and

- (b) if the Secretary relies upon such information in relation to the proposed suspension—must, in the case of information identified under subsection 14LA(1) of the Act, consult the giver of the information before giving the notice.

**34 Paragraph 35(3)(d)**

After “other persons”, insert “(each of whom is a *connected person*)”.

**35 Paragraph 35(3)(e)**

Omit “person mentioned in paragraph (d) with whom the applicant is connected or associated”, substitute “connected person who is a natural person”.

**36 After paragraph 35(3)(e)**

Insert:

- (ea) the following details in relation to each connected person that is a body corporate:
- (i) the name of the body corporate;
  - (ii) the body corporate’s ACN (if any);
  - (iii) the body corporate’s ABN (if any);
  - (iv) the body corporate’s ARBN (if any);
  - (v) the length of the connection or association with the body corporate;
  - (vi) the nature of the connection or association;

**37 Paragraph 35(3)(f)**

After “of each”, insert “natural”.

**38 Paragraph 35(3)(f)**

Omit “his or her own right or on someone else’s behalf”, substitute “the natural person’s own right or on behalf of another person”.

**39 After paragraph 35(3)(f)**

Insert:

- (fa) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate’s own right or on behalf of another person):
- (i) in relation to the applicant’s business that will undertake the activities;
- or
- (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant’s current income;

**40 Paragraph 35(3)(m)**

Omit “Act;”, substitute “Act.”.

**41 Paragraph 35(3)(n)**

Repeal the paragraph.

**42 Paragraph 35(4)(f)**

After “other persons”, insert “(each of whom is a *connected person*)”.

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**43 Paragraph 35(4)(g)**

Omit “person mentioned in paragraph (f) with whom the body corporate, its directors or officers are connected or associated”, substitute “connected person who is a natural person”.

**44 After paragraph 35(4)(g)**

Insert:

- (ga) the following details in relation to each connected person that is a body corporate:
  - (i) the name of that body corporate;
  - (ii) that body corporate’s ACN (if any);
  - (iii) that body corporate’s ABN (if any);
  - (iv) that body corporate’s ARBN (if any);
  - (v) the length of the connection or association with that body corporate;
  - (vi) the nature of the connection or association;
- (gb) the name and date of birth of each natural person who holds a relevant financial interest, or who is entitled to exercise a relevant power (whether in the natural person’s own right or on behalf of another person):
  - (i) in relation to the applicant’s business that will undertake the activities;
  - or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant’s current income;
- (gc) the name, ACN (if any), ABN (if any) and ARBN (if any) of each body corporate that holds a relevant financial interest, or that is entitled to exercise a relevant power (whether in the body corporate’s own right or on behalf of another person):
  - (i) in relation to the applicant’s business that will undertake the activities;
  - or
  - (ii) in relation to any other business of the applicant that provides a substantial proportion of the applicant’s current income;
- (gd) the following information in relation to each person who holds any relevant position (whether in his or her own right or on someone else’s behalf) in relation to the applicant’s business that will undertake the activities:
  - (i) the name and date of birth of the person;
  - (ii) the position in the business held by the person;

**45 At the end of paragraph 35(8)(b)**

Add:

- ; or (iii) if the drug is to be supplied to a person as mentioned in paragraph 37(c)—details of that supply and details of any arrangements in place between the applicant and that person relating to the proposed end use of the medicine referred to in that paragraph.

**46 Paragraph 36(2)(e)**

Repeal the paragraph.

**47 Paragraph 36(2)(f)**

Omit “environment;”, substitute “environment.”.

**48 Paragraph 36(2)(g)**

Repeal the paragraph.

**49 After section 36**

Insert:

**36A Application for manufacture licence—general grounds for refusal of licence**

For the purposes of paragraph 11J(1)(f) of the Act, a circumstance in which a licence must not be granted is if neither of the following apply:

- (a) the applicant for the licence will be carrying out the manufacture of the drug referred to in paragraph 11G(1)(a) of the Act;
- (b) one or more persons, under the direct supervision of the applicant for the licence, will be carrying out that manufacture.

**50 Section 37**

Repeal the section, substitute:

**37 Particular rules about manufacture licences involving cannabis etc.—  
medicinal cannabis products**

For the purposes of subparagraph 11K(2)(b)(iii) of the Act, the circumstances are that the drug will be supplied:

- (a) by a pharmacist in a public hospital in accordance with the *Therapeutic Goods Act 1989*; or
- (b) by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*; or
- (c) to a person who holds a licence under Part 3-3 of the *Therapeutic Goods Act 1989* for use by that person in the manufacture of a medicine (within the meaning of that Act), where one or more of the following apply:
  - (i) that medicine is to be supplied by a pharmacist in a public hospital in accordance with the *Therapeutic Goods Act 1989*;
  - (ii) that medicine is to be supplied in circumstances mentioned in subparagraph 11K(2)(b)(i) or (ii) of the Act;
  - (iii) that medicine is to be supplied by way of export from Australia in accordance with a licence and permission under the *Customs (Prohibited Exports) Regulations 1958*.

**51 Paragraph 38(2)(i)**

Omit “force;”, substitute “force.”.

**52 Paragraphs 38(2)(j) and (k)**

Repeal the paragraphs.

**53 Section 40**

Before “For the”, insert “(1)”.

**54 Section 40**

Omit “paragraph 12N(d)”, substitute “paragraph 12N(1)(d)”.

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**55 At the end of section 40**

Add:

- (2) For the purposes of paragraph 12N(2)(a) of the Act, the period for a matter covered by paragraph (1)(a), (b), (c), (d), (e) or (f) of this section is 72 hours starting when the matter comes to the attention of the licence holder.

**56 At the end of section 46**

Add:

- (6) If this section requires a notice to be given to a licence holder stating the reasons for a proposed suspension, the Secretary:
- (a) must not disclose information identified as sensitive law enforcement information under subsection 14LA(1) or (2) of the Act in the notice; and
  - (b) if the Secretary relies upon such information in relation to the proposed suspension—must, in the case of information identified under subsection 14LA(1) of the Act, consult the giver of the information before giving the notice.

**57 At the end of Division 2 of Part 5**

Add:

**56 Modification of operation of Chapters 2 and 3 of the Act**

For the purposes of paragraph 27(4)(g) of the Act:

- (a) paragraph 8G(1)(a) of the Act does not apply if the applicant for the medicinal cannabis licence is an agency of a State or Territory; and
- (b) paragraph 9F(1)(a) of the Act does not apply if the applicant for the cannabis research licence is an agency of a State or Territory; and
- (c) paragraph 10K(1)(a) of the Act does not apply if the holder of the cannabis licence is an agency of a State or Territory; and
- (d) paragraphs 10P(1)(b) and (c) of the Act do not apply if the holder of the cannabis licence is an agency of a State or Territory; and
- (e) paragraph 11J(1)(a) of the Act does not apply if the applicant for the manufacture licence is an agency of a State or Territory; and
- (f) paragraph 12N(1)(a) of the Act does not apply if the holder of the manufacture licence is an agency of a State or Territory; and
- (g) paragraphs 13B(1)(b) and (c) of the Act do not apply if the holder of the manufacture licence is an agency of a State or Territory.

**58 After Part 5**

Insert:

## Part 6—Application, saving and transitional provisions

### 57 Application provisions relating to the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*

- (1) The amendments of section 5 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 8E of the Act on or after the commencement of this section.
- (2) Sections 7A and 7B, as inserted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, apply in relation to applications made under section 8E of the Act on or after the commencement of this section.
- (3) The amendments of section 11 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 9D of the Act on or after the commencement of this section.
- (4) Section 13A, as inserted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to applications made under section 9D of the Act on or after the commencement of this section.
- (5) The amendments of sections 14 and 15 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 9N of the Act on or after the commencement of this section.
- (6) The amendment of section 19 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* applies in relation to medicinal cannabis licences granted under the Act on or after the commencement of this section.
- (7) Subsection 20(2), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to matters arising on or after the commencement of this section, whether the cannabis licences were granted under the Act before, on or after the commencement of this section.
- (8) Subsection 28(6), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to notices given under subsection 28(1) on or after the commencement of this section.
- (9) The amendments of sections 35 and 36 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 11G of the Act on or after the commencement of this section.
- (10) Section 36A, as inserted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to applications made under section 11G of the Act on or after the commencement of this section.
- (11) Section 37, as substituted by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to applications made under section 11G of the Act on or after the commencement of this section.
- (12) The amendments of section 38 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made under section 12 of the Act on or after the commencement of this section.
- (13) Subsection 40(2), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to matters arising on or after the



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commencement of this section, whether the manufacture licences were granted under the Act before, on or after the commencement of this section.

- (14) Subsection 46(6), as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to notices given under subsection 46(1) on or after the commencement of this section.
- (15) Section 56, as added by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018*, applies in relation to:
- (a) in the case of paragraphs 56(a), (b) and (e)—applications made on or after the commencement of this section; and
  - (b) in the case of paragraphs 56(c), (d), (f) and (g)—licences granted on or after the commencement of this section.
- (16) The amendments of clause 1 of Schedule 1 made by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* apply in relation to applications made on or after the commencement of this section.

**59 Clause 1 of Schedule 1 (table items 1 and 3)**

Omit “5,290”, substitute “5,040”.

**60 Clause 1 of Schedule 1 (table items 5 and 7)**

Omit “4,150”, substitute “3,900”.