



Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016

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 regulation.

Dated 27 October 2016

Peter Cosgrove
Governor-General

By His Excellency's Command

Sussan Ley
Minister for Health and Aged Care

Contents

1	Name.....	1
2	Commencement	1
3	Authority.....	1
4	Schedules.....	1
Schedule 1—Amendments		2
Part 1—Amendments to the Therapeutic Goods Regulations 1990		2
<i>Therapeutic Goods Regulations 1990</i>		2
Part 2—Amendments to the Crimes Regulations 1990		5
<i>Crimes Regulations 1990</i>		5

1 Name

This is the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016*.

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.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	29 October 2016
2. Schedule 1, Part 1	At the same time as the <i>Poisons Standard November 2016</i> commences. However, the provisions do not commence at all if that instrument does not commence.	1 November 2016
3. Schedule 1, Part 2	At the same time as Schedule 1 to the <i>Narcotic Drugs Amendment Act 2016</i> commences.	29 October 2016

Note: This table relates only to the provisions of this instrument as originally made.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 following:

- (a) the *Crimes Act 1914*;
- (b) the *Therapeutic Goods Act 1989*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Part 1—Amendments to the Therapeutic Goods Regulations 1990

Therapeutic Goods Regulations 1990

1 Subregulation 12A(1)

Repeal the subregulation, substitute:

- (1) For the purposes of subsection 18(1) of the Act, and subject to subregulation (2), all medicines are exempt from the operation of Part 3-2 of the Act (except section 31A and sections 31C to 31F), other than medicines that contain a substance covered by any of the following entries in the Poisons Standard:
 - (a) the entry for cannabidiol in Schedule 4;
 - (b) the entry for cannabis in Schedule 8;
 - (c) the entry for dronabinol in Schedule 8;
 - (d) the entry for nabilone in Schedule 8;
 - (e) the entry for nabiximols in Schedule 8;
 - (f) the entry for tetrahydrocannabinols in Schedule 8;
 - (g) an entry in Schedule 9.

2 Subregulation 12A(1A)

Omit “For subsection 32CA(2) of the Act, all biologicals are exempt, subject to subregulation (2),”, substitute “For the purposes of subsection 32CA(2) of the Act, and subject to subregulation (2), all biologicals are exempt”.

3 Subregulation 12A(2)

Omit “The exemption of a medicine or biological is subject to the following conditions”, substitute “The exemption of a medicine under subregulation (1), or of a biological under subregulation (1A), is subject to compliance with the following conditions”.

4 Schedule 5 (table item 1, column 2, after paragraph (a))

Insert:

- (aa) the goods do not contain a substance of a kind covered by any of the following entries in Schedule 8 to the Poisons Standard:
 - (i) cannabis;
 - (ii) dronabinol;
 - (iii) nabilone;
 - (iv) tetrahydrocannabinols; and

5 Schedule 5 (table item 6)

Repeal the item, substitute:

- 6 medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than:
 - (a) medicines that are used for gene therapy; or

- (b) medicines that:
 - (i) contain a substance covered by an entry in the Poisons Standard mentioned in any of paragraphs 12A(1)(a) to (f); and
 - (ii) are not dispensed, or extemporaneously compounded, in a public hospital in a State or a Territory for a person who is a patient in a public hospital in the State or Territory

6 Schedule 5A (cell at table item 5, column 2)

Repeal the cell, substitute:

Therapeutic goods, if:

- (a) the goods are not any of the following:
 - (i) biologicals;
 - (ii) goods referred to in item 3;
 - (iii) medicines that contain a substance covered by an entry in the Poisons Standard mentioned in any of paragraphs 12A(1)(a) to (f); and
- (b) the goods are manufactured by a person under a contract between the person and a private hospital, a public hospital in a State or Territory or a public institution (the *relevant institution*); and
- (c) the manufacture is in accordance with a formulation specified by the relevant institution; and
- (d) the goods are for use by, or in connection with, a patient of:
 - (i) the relevant institution; or
 - (ii) if the relevant institution is a public hospital in a State or Territory—another public hospital in the State or Territory

7 Schedule 5A (table item 5, column 3)

Omit “the private hospital, public hospital or public institution”, substitute “the relevant institution”.

8 Schedule 8 (cell at table item 2, column 3)

Repeal the cell, substitute:

- the manufacture of therapeutic goods, if:
- (a) the goods are not:
 - (i) biologicals; or
 - (ii) medicines that contain a substance covered by an entry in the Poisons Standard mentioned in any of paragraphs 12A(1)(a) to (f); and
 - (b) the goods are produced by the pharmacist:
 - (i) in a pharmacy where the pharmacist practices and the pharmacy is open to the public; or
 - (ii) on the premises of a dispensary conducted by a Friendly Society; or
 - (iii) on the premises of a private hospital; and
 - (c) the goods are for supply (other than by wholesale) on or from those premises

Part 2—Amendments to the Crimes Regulations 1990

Crimes Regulations 1990

9 Schedule 4 (at the end of the table)

Add:

25	The Secretary of the Department administered by the Minister administering the <i>National Health Act 1953</i>	Assessing whether a person is a fit and proper person to: (a) hold a licence (within the meaning of the <i>Narcotic Drugs Act 1967</i>); or (b) be associated with the holder of such a licence	All offences
----	--	--	--------------