



Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018

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 21 June 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 *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) 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.

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.	26 June 2018
2. Schedule 1, Parts 1 to 6	1 July 2018.	1 July 2018
3. Schedule 1, Part 7	Immediately after the commencement of item 16 of Part 2 of Schedule 1 to the <i>Therapeutic Goods (Fees and Other Measures) Regulations 2018</i> . However, the provisions do not commence at all if that item does not commence.	1 July 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Note: This table relates only to the provisions of this instrument as originally made.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 *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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

1 After Division 4.1B

Insert:

Division 4.1C—Conditions

4.3G Conditions applying automatically—information about poisons

- (1) This regulation applies to a conformity assessment certificate that covers a kind of medical device that contains a substance of a kind covered by an entry in a Schedule to the current Poisons Standard.
- (2) However, this regulation does not apply to the certificate if, under Appendix A to the current Poisons Standard, the Standard does not apply to poisons in that kind of device.
- (3) For the purposes of subsection 41EJ(5A) of the Act, the certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will not supply a medical device of that kind if the supply would contravene Part 2 of the current Poisons Standard.

2 At the end of Division 5.2

Add:

5.13 Conditions applying automatically—information about poisons (Act s 41FN)

- (1) This regulation applies in relation to a kind of medical device that contains a substance of a kind covered by an entry in a Schedule to the current Poisons Standard.
- (2) However, this regulation does not apply in relation to that kind of medical device if, under Appendix A to the current Poisons Standard, the Standard does apply to poisons in that kind of medical device.
- (3) For the purposes of subsection 41FN(5A) of the Act, the person in relation to whom a medical device of that kind is included in the Register must not supply the device in Australia if the supply would contravene Part 2 of the current Poisons Standard.

3 In the appropriate position in Part 11

Add:

Division 11.8—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018

11.35 Application—regulation 4.3G (conditions applying automatically to conformity assessment certificates)

Regulation 4.3G applies to a conformity assessment certificate issued before, on or after 1 July 2018.

11.36 Application—regulation 5.13 (conditions applying automatically to medical devices included in the Register)

Regulation 5.13 applies to a kind of medical device included in the Register before, on or after 1 July 2018.

Part 2—Variation of entries in Register

Therapeutic Goods Regulations 1990

4 Regulation 2 (definition of *TGA notifications process guidance document*)

Repeal the definition (including the note), substitute:

TGA notifications process guidance document means Version 3.0 of the document published by the Therapeutic Goods Administration entitled *Notifications process—requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected* (as in force on 1 July 2018).

Note: The TGA notifications process guidance document could in 2018 be viewed on the Therapeutic Goods Administration's website (<http://www.tga.gov.au>).

5 Subregulation 10AAB(2) (table item 6)

Repeal the item.

Part 3—Evaluation of prescription and other medicines

Therapeutic Goods Regulations 1990

6 Subregulation 16DA(1)

Omit “16C(3)(b) and 16D(3)(b)”, substitute “16C(3)(a) and (b) and 16D(3)(a) and (b)”.

7 Paragraph 16DA(1)(b)

Repeal the paragraph.

8 Before paragraph 16DA(2)(a)

Insert:

- (aa) the approval for the acceptable foreign approved medicine:
 - (i) is in force; and
 - (ii) was given not more than 12 months before the date of the application in relation to the evaluation;

Part 4—Homoeopathic preparations

Therapeutic Goods Regulations 1990

9 Schedule 4 (items 4A and 5)

Omit “homeopathic”, substitute “homoeopathic”.

10 Schedule 14 (item 6)

Omit “homeopathic”, substitute “homoeopathic”.

Part 5—Biologicals

Therapeutic Goods Regulations 1990

11 Regulation 2 (definition of *Class 2 biological*)

Repeal the definition, substitute:

Class 2 biological means a biological:

- (a) that:
 - (i) has been subjected to only minimal manipulation; and
 - (ii) is only for homologous use; and
 - (iii) is not mentioned in Schedule 16 as a Class 1, 3 or 4 biological; or
- (b) that is mentioned in Schedule 16 as a Class 2 biological.

12 Regulation 2 (definition of *Class 3 biological*)

Repeal the definition, substitute:

Class 3 biological means a biological:

- (a) that is not a Class 1, 2 or 4 biological; or
- (b) that is mentioned in Schedule 16 as a Class 3 biological.

13 Regulation 2 (definition of *Class 4 biological*)

Repeal the definition, substitute:

Class 4 biological means a biological that is mentioned in Schedule 16 as a Class 4 biological.

14 Regulation 2 (definition of *homologous use*)

Repeal the definition, substitute:

homologous use: see regulation 3B.

15 Regulation 2 (definition of *minimal manipulation*)

Repeal the definition, substitute:

minimal manipulation: see regulation 3B.

16 Regulation 2

Insert:

original cells or tissues: see regulation 3B.

17 At the end of Part 1

Add:

3B Definitions relating to goods comprising etc. human cells and tissues

- (1) This regulation applies to goods that comprise, contain, or are derived from human cells or tissues.
- (2) The human cells or tissues are the ***original cells or tissues***.

- (3) The goods have been subjected to *minimal manipulation* if no process or processes to which the goods have been subjected have altered any of the biological characteristics, physiological functions or structural properties of the original cells or tissues that are relevant to the purpose for which the manufacturer of the goods intends the goods to be used.
- (4) *Homologous use* of the goods is use of the goods to repair, reconstruct, replace or supplement the cells or tissues of a person (the *recipient*), if the goods will perform the same basic function or functions in the recipient as the original cells or tissues performed in the person from whom they were collected.

18 Regulation 16AB

After “of the Act”, insert “and item 14 of the table in Schedule 5A to these Regulations”.

19 Paragraphs 16AB(b) and (c)

Omit “biological”, substitute “relevant biological or other goods”.

20 In the appropriate position in Part 9

Add:

Division 9—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018

64 Definitions

In this Division:

Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018*.

finally determined has the same meaning as in Division 11.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

transitional goods means goods:

- (a) to which paragraph 4(q) of the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 applied on 30 June 2018; and
- (b) of a kind supplied in Australia on or before 30 June 2018; and
- (c) to which column 2 of item 14 of Schedule 5A to these Regulations, as inserted by the Amendment Regulations, does not apply.

65 Transitional provisions—exemptions from Parts 3-2 and 3-2A of the Act

Exemptions

- (1) For the purposes of subsections 18(1) and 32CA(2) of the Act, transitional goods are exempt from the operation of the following provisions of the Act:
 - (a) Part 3-2 (except sections 30EA, 31A and 31C to 31F);
 - (b) Division 4 of Part 3-2A.
- (2) The exemptions mentioned in subregulation (1) are subject to compliance with the condition that, if the sponsor of the goods knows that particular information

relating to an event or occurrence indicates that use of the goods as intended by the sponsor may have an unintended harmful effect, the sponsor must give the information to the Secretary within the period specified by regulation 16AB.

When exemptions cease

- (3) Subregulation (1) ceases to have effect on 1 July 2019, subject to subregulations (4) and (5).
- (4) If:
 - (i) a sponsor of transitional goods applies, on or before 30 June 2019, for registration, listing, or inclusion of the goods in the Register; and
 - (ii) the application passes preliminary assessment on or before 30 June 2019;subregulation (1) ceases to have effect in relation to the goods when the application is finally determined, lapses or is withdrawn, if that happens on or after 1 July 2019.
- (5) If a sponsor of transitional goods applies, on or before 30 June 2019, for an approval under section 32CK in relation to the goods, subregulation (1) ceases to have effect in relation to the goods when the application is finally determined or is withdrawn, if that happens on or after 1 July 2019.

Advertising offence and civil penalty

- (6) While subregulation (1) has effect in relation to transitional goods, paragraph 7(e) applies to the goods in the same way as that paragraph applies to goods mentioned in column 2 of an item in Schedule 5A.

66 Transitional provisions—exemptions from Part 3-3 of the Act

- (1) For the purposes of subsection 34(1) of the Act, transitional goods are exempt from the operation of Part 3-3 of the Act.
- (2) Subregulation (1) ceases to have effect on 1 July 2019, subject to subregulation (3).
- (3) If, on or before 30 June 2019, each person who carries out a step in the manufacture of transitional goods applies for a licence authorising the person to carry out the step on premises referred to in the application, subregulation (1) ceases to have effect in relation to the transitional goods produced by those persons carrying out the steps on those premises when the last of those applications is finally determined or is withdrawn, if that happens on or after 1 July 2019.

21 Schedule 5A (at the end of the table)

Add:

13	Therapeutic goods in relation to which all of the following paragraphs apply: (a) the goods comprise, contain or are derived from human cells or human tissues collected from a patient who is	if the sponsor knows that particular information relating to an event or occurrence indicates that use of the goods as intended by the sponsor may have an unintended harmful effect, the sponsor must give the information to the Secretary within the period specified by regulation 16AB
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- under the clinical care of a medical or dental practitioner;
- (b) the goods were manufactured by, or under the professional supervision of, the practitioner;
- (c) the single indication of the goods is homologous use:
 - (i) on that patient; and
 - (ii) in a single clinical procedure; and
 - (iii) by, or under the professional supervision of, that practitioner;
- (d) the goods have been subjected to only minimal manipulation;
- (e) the practitioner is registered in a State or internal Territory

22 Schedule 7 (at the end of the table)

Add:

- 21 Therapeutic goods in relation to which all of the following paragraphs apply:
- (a) the goods comprise, contain or are derived from human cells or human tissues collected from a patient who is under the clinical care of a medical or dental practitioner;
 - (b) the goods are manufactured by, or under the professional supervision of, the practitioner;
 - (c) the single indication of the goods is homologous use:
 - (i) on that patient; and
 - (ii) in a single clinical procedure; and
 - (iii) by, or under the professional supervision of, that practitioner;
 - (d) the goods have been subjected to only minimal manipulation;
 - (e) the practitioner is registered in a State or internal Territory

23 Schedule 16

Repeal the Schedule, substitute:

Schedule 16—Classes of biologicals

Note: See regulation 2.

1 Class 4 biologicals

For the purposes of the definition of *Class 4 biological* in regulation 2, the following biologicals are Class 4 biologicals:

- (a) biologicals that comprise or contain:
 - (i) live animal cells; or

- (ii) live animal tissues; or
- (iii) live animal organs;
- (b) biologicals to which both of the following paragraphs apply:
 - (i) the biologicals comprise, contain or are derived from human cells or human tissues that have been modified to artificially introduce a function or functions of the cells or tissues;
 - (ii) the artificially introduced function or functions were not intrinsic to the cells or tissues when they were collected from the donor;
- (c) pluripotent stem cells;
- (d) biologicals derived from pluripotent stem cells.

Part 6—Menstrual cups and tampons

Therapeutic Goods Regulations 1990

24 Schedule 5 (at the end of the table)

Add:

- 14 (a) tampons; and
(b) menstrual cups

25 Schedule 5A (at the end of the table)

Add:

- 14 Therapeutic goods in packs, if:
- (a) the packs contain tampons or menstrual cups; and
 - (b) any other therapeutic goods in the packs are included in the Register; and
 - (c) the packaging of any individually packaged medical devices or medicines in the pack is intact; and
 - (d) the packs do not contain any of the following:
 - (i) a biological;
 - (ii) a medicine mentioned in Part 1 of Schedule 10;
 - (iii) a medical device (other than an IVD medical device) that is classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class IIa or higher;
 - (iv) an IVD medical device or in-house IVD medical device that is classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class 2 or higher
- the packs must not be supplied:
- (a) by persons other than charities; or
 - (b) for a charge; or
 - (c) to persons other than homeless or disadvantaged women

26 Schedule 8 (at the end of the table)

Add:

7	charities	the manufacture of packs mentioned in item 14 of Schedule 5A
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Part 7—Variation fees for OTC medicines

Therapeutic Goods Regulations 1990

27 Clause 3 of Schedule 9 (table item 2CB)

Repeal the item, substitute:

2CB	Fee for a request under subsection 9D(2C) of the Act (other than a request to which item 2CC, 2CD or 2CE applies) to make one or more variations of one or more entries in the Register in relation to a medicine:	
	(a) for each entry, unless paragraph (b) applies	790
	(b) in the case of a single entry in the Register, if the request is made together with a request of a kind mentioned in item 5 of Part 3 in relation to the same entry	Nil

28 Clause 3 of Schedule 9 (table item 2CD)

Repeal the item, substitute:

2CD	Fee for a request under subsection 9D(2C) of the Act to make the same variation or variations of 2 or more entries in the Register that each relate to a registered OTC medicine:	
	(a) for each group of up to 7 entries, unless paragraph (b) applies	790
	(b) for each group of up to 20 entries, if the request is made together with a request of a kind mentioned in item 5 of Part 3, in relation to the same group of entries	Nil

29 Clause 4 of Schedule 9 (table items 5 and 6)

Repeal the items, substitute:

5	Application fee under paragraph 9D(7)(f) of the Act, for any of the following requests in relation to up to 20 entries in the Register:	
	(a) a C1 (section 9D) application	1,620
	(b) a C2 (section 9D) application	5,620
	(c) a C3 (section 9D) application	8,330
	(d) a C4 (section 9D) application	11,400