Therapeutic Goods Legislation Amendment (2018 Measures No. 3) 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 11 October 2018

Peter Cosgrove
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

OPC63444 - A

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) 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.	16 October 2018
2. Schedule 1, Parts 1 to 7	The day after this instrument is registered.	16 October 2018
3. Schedule 1, Part 8	1 January 2019.	1 January 2019

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Fees for Class I medical devices for export only

Division 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Part 1 of Schedule 5 (table item 1.5)

Repeal the item, substitute:

1.5	Application for the following kinds of medical devices to be included in the Register:	Paragraph 41FDB(2)(b) of the Act	
	(a) a Class AIMD medical device;		1,310
	(b) a Class III medical device;		1,310
	(c) a Class IIb medical device;		1,020
	(d) a Class IIa medical device;		1,020
	(e) a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function, except a device that is intended by the manufacturer to be for export only;		1,020
	(f) a Class I medical device that is intended by the manufacturer to be for export only;		90
	(g) a Class I medical device except one described in paragraph (e) or (f);		530
	(h) an IVD medical device, including a Class 4 in-house IVD medical device but not a Class 2 IVD medical device that was, immediately before the commencement of the *Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015*: (i) included in the Register; and (ii) classified as a Class 3 IVD medical device because of subclause 1.3(2) of Schedule 2A (as in force immediately before the commencement of that regulation)		1,020
	Note: Paragraph (h)—there is no fee for an application to include in the Register a Class 2 IVD medical device mentioned in the paragraph.		

Division 2—Application of amendments made by Division 1

Therapeutic Goods (Medical Devices) Regulations 2002

2 In the appropriate position in Part 11

Insert:

Division 11.9—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018

11.37 Application of table item 1.5 in Part 1 of Schedule 5

(1) Table item 1.5 in Part 1 of Schedule 5, as amended by the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018*, applies in relation to applications made on or after 1 July 2018.

(2) If, on or after 1 July 2018 and before the commencement of Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018*, a person:

(a) applied for the inclusion in the Register of a Class I medical device intended by the manufacturer to be for export only; and

(b) paid the fee prescribed in relation to that application by table item 1.5 in Part 1 of Schedule 5 to these Regulations as in force before that commencement;

the Secretary must refund to the person the difference between the fee paid and the fee prescribed in relation to the application by that table item as in force after that commencement.

Part 2—Disinfectants

Division 1—Main amendments

Therapeutic Goods Regulations 1990

3 Part 1 of Schedule 3 (table item 3, column headed "Therapeutic goods")

Omit ", other than devices of a kind mentioned in Part 2,".

4 Part 2 of Schedule 3

Repeal the Part.

5 Schedule 4 (table item 2, column headed "Therapeutic goods", paragraph (aa))

Repeal the paragraph.

6 Schedule 4 (table item 16)

Repeal the item, substitute:

16	hospital grade disinfectants, or household grade disinfectants, that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides

7 Schedule 5 (table item 8, column 2, paragraph (f))

Repeal the paragraph, substitute:

(f) disinfectants, except those described in item 16 in Schedule 4;

8 Clause 3 of Schedule 9 (table item 2, column 2, paragraph (b))

Repeal the paragraph.

9 Clause 3 of Schedule 9 (table item 2, column 3)

Omit "1,460" (first occurring).

10 Clause 3 of Schedule 9 (table item 2, column 2, paragraph (h))

Repeal the paragraph.

11 Clause 3 of Schedule 9 (table item 2, column 3)

Omit "730".

12 Clause 3 of Schedule 9 (table item 2A, column 2, paragraph (d))

Repeal the paragraph.

13 Clause 3 of Schedule 9 (table item 2A, column 3)

Omit "450" (first occurring).

14 Clause 3 of Schedule 9 (table item 2A, column 2, paragraph (e))

Omit ", other than a device mentioned in paragraph (d)".

15 Clause 3 of Schedule 9 (table item 5B)

Repeal the item.

Division 2—Application of amendments made by Division 1

Therapeutic Goods Regulations 1990

16 In the appropriate position in Part 9

Insert:

Division 10—Application provisions relating to the Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018

67 Application

The amendments of Schedules 3, 4 and 5 made by Division 1 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 3) Regulations 2018* apply to disinfectants after the commencement of that Division, whether or not the disinfectants were registered goods or listed goods immediately before that commencement.

Note: If disinfectants were registered goods immediately before that commencement, subregulation 10B(2) lets the persons in whose names the goods were entered in the Register immediately before that commencement apply to the Secretary:

(a) to transfer the entry for the goods to the part of the Register for listed goods; or

(b) to retain the entry in the part of the Register for registered goods.

Part 3—Human cells and tissues

Therapeutic Goods Regulations 1990

17 Regulation 16AB

Omit "14", substitute "13".

18 Regulation 64 (paragraph (c) of the definition of *transitional goods*)

Omit "14", substitute "13".

Part 4—Instalments of fees for biologicals

Therapeutic Goods Regulations 1990

19 Subparagraph 45AA(4)(c)(ii)

After "device", insert "or refuses the application to include the biological in the Register".

20 Subparagraph 45AA(4)(c)(ii)

After "25(3)", insert "or section 32DG".

21 At the end of subparagraph 45AA(4)(c)(iii)

Add "or the biological is included in the Register".

Part 5—Sunscreen preparations with certain indications

Division 1—Main amendments

Therapeutic Goods Regulations 1990

22 Schedule 4 (at the end of the cell at table item 7, column headed "Therapeutic goods")

Add:

; and (e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and

(f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened

Division 2—Related amendments

Therapeutic Goods Regulations 1990

23 Subparagraph 3AA(d)(i)

Omit "contains indications", substitute "has indications".

24 Schedule 4 (table item 3, column headed "Therapeutic goods", paragraph (d))

Omit "contains indications", substitute "has indications".

25 Schedule 4 (table item 4A, column headed "Therapeutic goods", paragraph (f))

Omit "contains indications", substitute "has indications".

26 Schedule 4 (table item 5, column headed "Therapeutic goods", paragraph (e))

Omit "contains indications", substitute "has indications".

Part 6—Applications to list medicines under section 26AE of the Act

Therapeutic Goods Regulations 1990

27 Regulation 2 (definition of *L(A)1 application*)

Omit "complementary".

28 Regulation 2 (definition of *L(A)2 application*)

Omit "complementary".

29 Regulation 2 (definition of *L(A)3 application*)

Omit "complementary".

30 Division 4 of Part 3A (at the end of the heading)

Add "**and certain other listed medicines**".

31 Regulation 16GH (heading)

Omit "**complementary**".

32 Regulation 16GJ

Omit "complementary".

33 Part 4 of Schedule 9 (at the end of the heading)

Add "**and certain other listed medicines**".

34 Clause 5 of Schedule 9

Omit "complementary".

Part 7—Correction, and repeal of spent provision

Therapeutic Goods (Medical Devices) Regulations 2002

35 Subregulation 5.3(3)

Repeal the subregulation.

36 Subregulation 5.13(2)

After "Standard does", insert "not".

Part 8—Advertising

Therapeutic Goods Regulations 1990

37 Regulation 2 (definition of *Therapeutic Goods Advertising Code*)

Repeal the definition.

38 Paragraph 6B(1)(b)

Omit "in Part 1 of Appendix 6 to", substitute "described in section 30 of".

39 Regulation 8

Omit "subsections 4(1), (2), (3), (4), (5) and (6)", substitute "sections 9, 10, 15, 16, 18, 19 and 21".

40 At the end of regulation 8

Add:

Note: The application of those sections is affected by section 6 of the Code.

41 Part 1 of Schedule 2 (table item 1)

Repeal the item.

42 Part 1 of Schedule 2 (table item 4, column 2)

Omit "subparagraph 7(1)(e)(i) or (ii)", substitute "subsection 24(2)".

43 Part 1 of Schedule 2 (table item 8, column 2)

Omit "paragraph 7(2)(a) or (b)", substitute "section 25".

44 Part 1 of Schedule 3 (table item 2A, column headed "Therapeutic goods", paragraph (a))

After "8,", insert "8A,".

45 Schedule 4 (table item 7, column headed "Therapeutic goods")

Omit "(other than preparations for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code)".

46 Schedule 4 (table item 8, column headed "Therapeutic goods", subparagraph (d)(ii))

Omit "form of a disease, condition, ailment or defect identified in a part of the Therapeutic Goods Advertising Code as a serious form of a disease, condition, ailment or defect", substitute "serious form, within the meaning of subsection 28(1) of the Therapeutic Goods Advertising Code, of a disease, condition, ailment or defect".

47 Schedule 5 (table item 8, column 2)

Omit "medicines unless the indications proposed by the sponsor are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code", substitute "goods, unless the goods are for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect".

48 Schedule 5 (table item 8, column 2, paragraph (e))

Repeal the paragraph.

49 Schedule 5 (after table item 8)

Insert:

8A	Lotions, shampoos or hairdressings for the prevention or treatment of dandruff, except those that: (a) are included in a Schedule to the Poisons Standard; or (b) are also for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, another disease, condition, ailment or defect