



Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019

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 March 2019

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 (Fees and Other Measures) Regulations 2019*.

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 March 2019
2. Schedule 1, Parts 1 and 2	1 July 2019.	1 July 2019
3. Schedule 1, Part 3	Immediately after the commencement of Part 3 of Schedule 1 to the <i>Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018</i> .	1 July 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 commencing 1 July 2019

Part 1—Fees

Therapeutic Goods (Medical Devices) Regulations 2002

1 Part 1 of Schedule 5 (table item 1.5, column headed “Matter”, paragraph (h))

Omit “but not”, substitute “, but not a device that is intended by the manufacturer to be for export only or”.

2 Part 1 of Schedule 5 (at the end of table item 1.5)

Add:

- | | |
|--|----|
| (i) an IVD medical device that is intended
by the manufacturer to be for export
only | 90 |
|--|----|

3 Amendments of listed provisions

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Schedule 5, Part 1, item 1.1	1,000	1,020
2	Schedule 5, Part 1, item 1.1A	9,840	10,000
3	Schedule 5, Part 1, item 1.2, paragraph (a)	8,620	8,800
4	Schedule 5, Part 1, item 1.2, paragraph (b)	8,670	8,850
5	Schedule 5, Part 1, item 1.3, paragraph (a)	52,700	53,800
6	Schedule 5, Part 1, item 1.3, paragraph (b)	40,700	41,500
7	Schedule 5, Part 1, item 1.3A, paragraph (a)	29,800	30,400
8	Schedule 5, Part 1, item 1.3A, paragraph (b)	63,400	64,700
9	Schedule 5, Part 1, item 1.3A, paragraph (c)	15,400	15,700
10	Schedule 5, Part 1, item 1.3A, paragraph (d)	3,740	3,820
11	Schedule 5, Part 1, item 1.3A, paragraph (e)	41,100	41,900
12	Schedule 5, Part 1, item 1.3A, paragraph (f)	26,200	26,700
13	Schedule 5, Part 1, item 1.4A	4,480	4,570
14	Schedule 5, Part 1, items 1.4B and 1.4C	2,460	2,510
15	Schedule 5, Part 1, item 1.4D	73,100	74,600
16	Schedule 5, Part 1, items 1.4E and 1.4F	52,500	53,600
17	Schedule 5, Part 1, item 1.5, paragraphs (a) and (b)	1,310	1,340
18	Schedule 5, Part 1, item 1.5, paragraphs (c), (d) and (e)	1,020	1,040
19	Schedule 5, Part 1, item 1.5, paragraph (g)	530	540
20	Schedule 5, Part 1, item 1.5, paragraph (h)	1,020	1,040
21	Schedule 5, Part 1, item 1.5A	9,840	10,000
22	Schedule 5, Part 1, item 1.7	18,200	18,600
23	Schedule 5, Part 1, item 1.8	360	370
24	Schedule 5, Part 1, item 1.9, paragraph (a)	29,700	30,300

Amendments relating to fees			
Item	Provision	Omit	Substitute
25	Schedule 5, Part 1, item 1.9, paragraph (b)	58,300	59,500
26	Schedule 5, Part 1, item 1.9, paragraph (c)	40,700	41,500
27	Schedule 5, Part 1, item 1.9, paragraph (d)	28,400	29,000
28	Schedule 5, Part 1, item 1.9, paragraph (e)	26,000	26,500
29	Schedule 5, Part 1, item 1.9, paragraph (f)	22,200	22,700
30	Schedule 5, Part 1, item 1.9A, paragraph (a)	29,800	30,400
31	Schedule 5, Part 1, item 1.9A, paragraph (b)	63,400	64,700
32	Schedule 5, Part 1, item 1.9A, paragraph (c)	15,400	15,700
33	Schedule 5, Part 1, item 1.9A, paragraph (d)	3,740	3,820
34	Schedule 5, Part 1, item 1.9A, paragraph (e)	41,100	41,900
35	Schedule 5, Part 1, item 1.9A, paragraph (f)	26,200	26,700
36	Schedule 5, Part 1, item 1.10, paragraph (a)	17,800	18,200
37	Schedule 5, Part 1, item 1.10, paragraph (b)	35,200	35,900
38	Schedule 5, Part 1, item 1.10, paragraph (c)	24,500	25,000
39	Schedule 5, Part 1, item 1.10, paragraph (d)	15,400	15,700
40	Schedule 5, Part 1, item 1.10, paragraph (e)	13,500	13,800
41	Schedule 5, Part 1, item 1.12	420	430
42	Schedule 5, Part 1, item 1.13	3,830	3,910
43	Schedule 5, Part 1, item 1.14	7,030	7,170
44	Schedule 5, Part 1, item 1.14A	6,850	6,990
45	Schedule 5, Part 1, item 1.14B	63,400	64,700
46	Schedule 5, Part 1, item 1.14C	15,400	15,700
47	Schedule 5, Part 1, item 1.15	450	460
48	Schedule 5, Part 1, item 1.17	1,020	1,040
49	Schedule 5, Part 2, paragraph 2.1(b)	420	430

Therapeutic Goods Regulations 1990

4 Regulation 2

Insert:

L(A)C1 (section 9D) request means a request under subsection 9D(1), (2) or (3) of the Act for a variation that:

- (a) is of information included in an entry in the Register relating to a medicine that is listed under section 26AE of the Act; and
- (b) is of a kind specified in the changes table as an L(A)C1 (section 9D) level change.

L(A)C1 (section 23) application means an application made under section 23 of the Act for the listing under section 26AE of the Act of a medicine (the ***new medicine***), if:

- (a) the new medicine is a changed form of a medicine (the ***existing medicine***) listed under section 26AE of the Act; and

- (b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
- (c) the change is of a kind specified in the changes table as an L(A)C1 (section 23) level change.

L(A)C2 (section 9D) request means a request under subsection 9D(1), (2) or (3) of the Act for a variation that:

- (a) is of information included in an entry in the Register relating to a medicine that is listed under section 26AE of the Act; and
- (b) is of a kind specified in the changes table as an L(A)C2 (section 9D) level change.

L(A)C2 (section 23) application means an application made under section 23 of the Act for the listing under section 26AE of the Act of a medicine (the *new medicine*), if:

- (a) the new medicine is a changed form of a medicine (the *existing medicine*) listed under section 26AE of the Act; and
- (b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
- (c) the change is of a kind specified in the changes table as an L(A)C2 (section 23) level change.

L(A)CN (section 9D) request means a request under subsection 9D(1), (2) or (3) of the Act for a variation that:

- (a) is of information included in an entry in the Register relating to a medicine that is listed under section 26AE of the Act; and
- (b) is of a kind specified in the changes table as an L(A)CN (section 9D) level change.

L(A)CN (section 23) application means an application made under section 23 of the Act for the listing under section 26AE of the Act of a medicine (the *new medicine*), if:

- (a) the new medicine is a changed form of a medicine (the *existing medicine*) listed under section 26AE of the Act; and
- (b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
- (c) the change is of a kind specified in the changes table as an L(A)CN (section 23) level change.

5 Regulation 2 (paragraphs (a), (b) and (c) of the definition of RCMC1 (section 23) application)

Repeal the paragraphs, substitute:

- (a) the new medicine is a changed form of a registered complementary medicine (the *existing medicine*); and
- (b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and

- (c) the change is of a kind specified in the changes table as an RCMC1 (section 23) level change.

6 Regulation 2 (paragraphs (a), (b) and (c) of the definition of RCMC2 (section 23) application)

Repeal the paragraphs, substitute:

- (a) the new medicine is a changed form of a registered complementary medicine (the *existing medicine*); and
(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
(c) the change is of a kind specified in the changes table as an RCMC2 (section 23) level change.

7 Regulation 2 (paragraphs (a), (b) and (c) of the definition of RCMC3 (section 23) application)

Repeal the paragraphs, substitute:

- (a) the new medicine is a changed form of a registered complementary medicine (the *existing medicine*); and
(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
(c) the change is of a kind specified in the changes table as an RCMC3 (section 23) level change.

8 Regulation 2 (paragraphs (a), (b) and (c) of the definition of RCMC4 (section 23) application)

Repeal the paragraphs, substitute:

- (a) the new medicine is a changed form of a registered complementary medicine (the *existing medicine*); and
(b) the new medicine and the existing medicine are separate and distinct for the purposes of Part 3-2 of the Act, but the new medicine forms part of the same gazetted therapeutic goods group as the existing medicine; and
(c) the change is of a kind specified in the changes table as an RCMC4 (section 23) level change.

9 After paragraph 10AA(1)(d)

Insert:

- (da) the definition of *L(A)C1 (section 9D) request*;
(db) the definition of *L(A)C2 (section 9D) request*;
(dc) the definition of *L(A)CN (section 9D) request*;

10 Subregulation 16GG(2) (before table item 1)

Insert:

1A	L(A)C1 (section 9D) request	Within 40 working days after the Secretary receives the request	Within 30 working days after the Secretary notifies the applicant that the request has been accepted
1B	L(A)C2 (section 9D) request	Within 40 working days after the Secretary	Within 120 working days after the Secretary notifies the applicant that the

receives the request request has been accepted

11 Subregulation 16GH(1) (after table item 3)

Insert:

3A	L(A)C1 (section 23) application	Within 40 working days after the Secretary receives the application	Within 30 working days after the Secretary notifies the applicant that the application has passed preliminary assessment
3B	L(A)C2 (section 23) application	Within 40 working days after the Secretary receives the application	Within 120 working days after the Secretary notifies the applicant that the application has passed preliminary assessment

12 Regulation 43ACA (heading)

Omit “registered complementary”, substitute “certain registered and listed”.

13 Paragraph 43ACA(1)(a)

Omit “an application of a kind mentioned in item”, substitute “a request of a kind mentioned in item 1A, 1B,”.

14 Paragraphs 43ACA(1)(b) and (c)

Omit “of the application”, substitute “of the request”.

15 Before paragraph 43ACA(2)(a)

Insert:

(aa) for an L(A)C1 (section 9D) request—\$1,070;

(ab) for an L(A)C2 (section 9D) request—\$7,770;

16 Regulation 43AF (heading)

Omit “registered complementary”, substitute “certain registered and listed”.

17 Before subparagraph 43AF(b)(i)

Insert:

(ia) an L(A)C1 (section 9D) request; or

(ib) an L(A)C2 (section 9D) request; or

18 Clause 2 of Schedule 9 (at the end of the heading)

Add “or 4”.

19 At the end of clause 2 of Schedule 9

Add “or 4”.

20 Clause 5 of Schedule 9 (before table item 1)

Insert:

1A	Application fee under paragraph 9D(7)(f) of the Act for an L(A)C1 (section 9D) request	1,990
1B	Application fee under paragraph 9D(7)(f) of the Act for an L(A)C2 (section 9D) request	8,690
1C	Application fee under paragraph 9D(7)(f) of the Act for an L(A)CN (section 9D)	790

	request	
1D	Application fee under paragraph 23B(2)(b) of the Act for an L(A)C1 (section 23) application	920
1E	Application fee under paragraph 23B(2)(b) of the Act for an L(A)C2 (section 23) application	920
1F	Application fee under paragraph 23B(2)(b) of the Act for an L(A)CN (section 23) application	790
1G	Evaluation fee under subsection 26AC(2) of the Act for an L(A)C1 (section 23) application	1,070
1H	Evaluation fee under subsection 26AC(2) of the Act for an L(A)C2 (section 23) application	7,770

21 Amendments of listed provisions

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Paragraph 43AAJ(1)(b)	97,900	99,900
2	Paragraph 43AC(2)(a)	4,000	4,080
3	Paragraph 43AC(2)(b)	6,710	6,850
4	Paragraph 43AC(2)(c)	8,750	8,930
5	Paragraph 43ACA(2)(a)	4,040	4,120
6	Paragraph 43ACA(2)(b)	6,310	6,440
7	Paragraph 43ACA(2)(c)	9,330	9,520
8	Paragraph 45(6)(a)	1,100	1,120
9	Paragraph 45(6)(b)	4,360	4,450
10	Schedule 9, clause 3, item 1A	470	480
11	Schedule 9, clause 3, item 1, paragraph (a)	1,720	1,760
12	Schedule 9, clause 3, item 1, paragraph (b)	21,500	21,900
13	Schedule 9, clause 3, item 1, paragraph (c)	18,200	18,600
14	Schedule 9, clause 3, item 1, paragraph (d)	2,740	2,800
15	Schedule 9, clause 3, item 1AA	12,500	12,800
16	Schedule 9, clause 3, item 1AB	4,520	4,610
17	Schedule 9, clause 3, item 1AC, paragraph (a)	47,900	48,900
18	Schedule 9, clause 3, item 1AC, paragraph (b)	28,600	29,200
19	Schedule 9, clause 3, item 1AD, paragraph (a)	250,200	255,300
20	Schedule 9, clause 3, item 1AD, paragraph (b)	165,000	168,400
21	Schedule 9, clause 3, item 1AE	28,500	29,100
22	Schedule 9, clause 3, item 1AF	120,300	122,800
23	Schedule 9, clause 3, item 1AG	17,200	17,600
24	Schedule 9, clause 3, item 1B	12,500	12,800
25	Schedule 9, clause 3, item 2, paragraph (ba)	47,800	48,800
26	Schedule 9, clause 3, item 2, paragraph (bb)	15,900	16,200
27	Schedule 9, clause 3, item 2, paragraph (bc)	31,900	32,600
28	Schedule 9, clause 3, item 2, paragraph (bca)	50,700	51,700
29	Schedule 9, clause 3, item 2, paragraph (bd)	28,500	29,100

Schedule 1 Amendments commencing 1 July 2019**Part 1** Fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
30	Schedule 9, clause 3, item 2, subparagraph (be)(i)	9,490	9,680
31	Schedule 9, clause 3, item 2, subparagraph (be)(ii)	6,190	6,320
32	Schedule 9, clause 3, item 2, subparagraph (bf)(i)	19,100	19,500
33	Schedule 9, clause 3, item 2, subparagraph (bf)(ii)	12,400	12,700
34	Schedule 9, clause 3, item 2, paragraph (bfa)	30,200	30,800
35	Schedule 9, clause 3, item 2, paragraph (bg)	18,400	18,800
36	Schedule 9, clause 3, item 2, paragraph (bh)	3,020	3,080
37	Schedule 9, clause 3, item 2, paragraph (bi)	18,600	19,000
38	Schedule 9, clause 3, item 2, paragraphs (bj) and (bk)	1,100	1,120
39	Schedule 9, clause 3, item 2, paragraph (c)	4,350	4,440
40	Schedule 9, clause 3, item 2, paragraph (d)	2,180	2,220
41	Schedule 9, clause 3, item 2, paragraph (d)	12,600	12,900
42	Schedule 9, clause 3, item 2, paragraph (g)	1,460	1,490
43	Schedule 9, clause 3, item 2A, paragraph (a)	1,680	1,710
44	Schedule 9, clause 3, item 2A, paragraph (c)	420	430
45	Schedule 9, clause 3, item 2A, paragraphs (e), (f) and (g)	450	460
46	Schedule 9, clause 3, item 2AB	430	440
47	Schedule 9, clause 3, item 2AC	1,100	1,120
48	Schedule 9, clause 3, item 2B	5,460	5,570
49	Schedule 9, clause 3, item 2C	4,360	4,450
50	Schedule 9, clause 3, item 2CA	5,460	5,570
51	Schedule 9, clause 3, items 2CB, 2CC and 2CD	790	810
52	Schedule 9, clause 3, item 2CE, paragraphs (a) and (b)	790	810
53	Schedule 9, clause 3, item 3, paragraph (a)	450	460
54	Schedule 9, clause 3, item 3, paragraph (b)	820	840
55	Schedule 9, clause 3, item 3AB, paragraphs (a) and (b)	420	430
56	Schedule 9, clause 3, item 4, paragraph (a)	191,800	195,700
57	Schedule 9, clause 3, item 4, subparagraphs (aa)(i) and (ii)	64,000	65,300
58	Schedule 9, clause 3, item 4, subparagraph (aa)(iii)	127,600	130,200
59	Schedule 9, clause 3, item 4, paragraph (ab)	202,800	207,000
60	Schedule 9, clause 3, item 4, paragraph (b)	113,800	116,100
61	Schedule 9, clause 3, item 4, subparagraph (bb)(i)	37,900	38,700
62	Schedule 9, clause 3, item 4, subparagraph (bb)(i)	24,600	25,100
63	Schedule 9, clause 3, item 4, subparagraph (bb)(ii)	37,900	38,700
64	Schedule 9, clause 3, item 4, subparagraph (bb)(ii)	24,600	25,100
65	Schedule 9, clause 3, item 4, subparagraph (bb)(iii)	75,800	77,400
66	Schedule 9, clause 3, item 4, subparagraph (bb)(iii)	49,600	50,600
67	Schedule 9, clause 3, item 4, paragraph (bc)	4,350	4,450
68	Schedule 9, clause 3, item 4, paragraph (bd)	120,600	123,100
69	Schedule 9, clause 3, item 4, paragraph (c)	73,200	74,700
70	Schedule 9, clause 3, item 4, paragraph (d)	12,100	12,300

Amendments relating to fees			
Item	Provision	Omit	Substitute
71	Schedule 9, clause 3, item 4, paragraph (g)	74,200	75,700
72	Schedule 9, clause 3, item 4, paragraph (h)	4,360	4,450
73	Schedule 9, clause 3, item 6, paragraph (a)	32,000	32,700
74	Schedule 9, clause 3, item 6, paragraphs (b), (c) and (ca)	21,800	22,200
75	Schedule 9, clause 3, item 6, paragraph (d)	36,600	37,400
76	Schedule 9, clause 3, item 6AB	690	700
77	Schedule 9, clause 3, item 6AC	1,160	1,180
78	Schedule 9, clause 3, item 6AD, paragraph (a)	21,800	22,200
79	Schedule 9, clause 3, item 6AD, paragraph (b)	5,460	5,570
80	Schedule 9, clause 3, item 6B	3,660	3,740
81	Schedule 9, clause 3, item 6C	7,950	8,110
82	Schedule 9, clause 3, item 6D, paragraph (a)	10,500	10,700
83	Schedule 9, clause 3, item 6D, paragraph (b)	13,500	13,800
84	Schedule 9, clause 3, item 6D, paragraph (c)	18,400	18,800
85	Schedule 9, clause 3, item 6D, paragraph (d)	24,400	24,900
86	Schedule 9, clause 3, item 6D, paragraph (e)	36,600	37,400
87	Schedule 9, clause 3, item 6D, paragraph (f)	48,800	49,800
88	Schedule 9, clause 3, item 6D, paragraph (g)	73,200	74,700
89	Schedule 9, clause 3, item 7, paragraph (a)	10,900	11,100
90	Schedule 9, clause 3, item 7, paragraphs (b), (c) and (ca)	9,080	9,270
91	Schedule 9, clause 3, item 7, paragraph (d)	36,600	37,400
92	Schedule 9, clause 3, item 7, paragraphs (e) and (f)	9,080	9,270
93	Schedule 9, clause 3, item 7A, paragraph (a)	10,500	10,700
94	Schedule 9, clause 3, item 7A, subparagraph (b)(i)	10,500	10,700
95	Schedule 9, clause 3, item 7A, subparagraph (b)(ii)	13,500	13,800
96	Schedule 9, clause 3, item 7A, subparagraph (b)(iii)	18,400	18,800
97	Schedule 9, clause 3, item 7A, subparagraph (b)(iv)	24,400	24,900
98	Schedule 9, clause 3, item 7A, subparagraph (b)(v)	36,600	37,400
99	Schedule 9, clause 3, item 7A, subparagraph (b)(vi)	48,800	49,800
100	Schedule 9, clause 3, item 7A, subparagraph (b)(vii)	73,200	74,700
101	Schedule 9, clause 3, item 7B, paragraph (a)	10,500	10,700
102	Schedule 9, clause 3, item 7B, subparagraph (b)(i)	10,500	10,700
103	Schedule 9, clause 3, item 7B, subparagraph (b)(ii)	13,500	13,800
104	Schedule 9, clause 3, item 7B, subparagraph (b)(iii)	18,400	18,800
105	Schedule 9, clause 3, item 7B, subparagraph (b)(iv)	24,400	24,900
106	Schedule 9, clause 3, item 7B, subparagraph (b)(v)	36,600	37,400
107	Schedule 9, clause 3, item 7B, subparagraph (b)(vi)	48,800	49,800
108	Schedule 9, clause 3, item 7B, subparagraph (b)(vii)	73,200	74,700
109	Schedule 9, clause 3, item 7C	1,040	1,060
110	Schedule 9, clause 3, item 8, paragraph (a)	770	790
111	Schedule 9, clause 3, item 8, paragraph (b)	1,020	1,040

Schedule 1 Amendments commencing 1 July 2019**Part 1** Fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
112	Schedule 9, clause 3, items 8A, 8B and 8C	770	790
113	Schedule 9, clause 3, item 9, paragraph (a)	970	990
114	Schedule 9, clause 3, item 9, paragraph (b)	1,360	1,390
115	Schedule 9, clause 3, item 9AA	670	680
116	Schedule 9, clause 3, item 9AB	900	920
117	Schedule 9, clause 3, items 9AC and 9ACA	670	680
118	Schedule 9, clause 3, item 9AD, paragraph (a)	1,310	1,340
119	Schedule 9, clause 3, item 9AD, paragraph (b)	11,200	11,400
120	Schedule 9, clause 3, item 9AD, paragraph (c)	25,100	25,600
121	Schedule 9, clause 3, item 9AD, paragraph (d)	33,700	34,400
122	Schedule 9, clause 3, item 9AD, paragraph (e)	52,600	53,700
123	Schedule 9, clause 3, item 9AD, paragraph (f)	70,100	71,500
124	Schedule 9, clause 3, item 9AD, paragraph (g)	85,500	87,300
125	Schedule 9, clause 3, items 9B and 9C	18,200	18,600
126	Schedule 9, clause 3, items 14 and 14A, paragraphs (a) and (b)	360	370
127	Schedule 9, clause 3, item 17, subparagraph (a)(i)	250	260
128	Schedule 9, clause 3, item 17, subparagraph (a)(ii)	300	310
129	Schedule 9, clause 3, item 17, subparagraph (a)(iii)	470	480
130	Schedule 9, clause 3, item 17A, subparagraph (a)(i)	1,190	1,210
131	Schedule 9, clause 3, item 17A, subparagraph (a)(ii)	630	640
132	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(iii)(A)	900	920
133	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(iii)(B)	250	260
134	Schedule 9, clause 3, item 17A, subparagraph (a)(iv)	440	450
135	Schedule 9, clause 3, item 17A, subparagraph (a)(v)	310	320
136	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(vi)(A)	250	260
137	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(vi)(B)	300	310
138	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(vi)(C)	470	480
139	Schedule 9, clause 3, item 18	2,210	2,260
140	Schedule 9, clause 4, item 1, paragraphs (a) and (b)	1,620	1,650
141	Schedule 9, clause 4, item 1, paragraph (c)	2,600	2,650
142	Schedule 9, clause 4, item 1, paragraph (d)	3,790	3,870
143	Schedule 9, clause 4, item 1, paragraph (e)	5,620	5,740
144	Schedule 9, clause 4, item 1, paragraphs (f), (g) and (h)	1,620	1,650
145	Schedule 9, clause 4, item 1, paragraph (i)	2,600	2,650
146	Schedule 9, clause 4, item 2, paragraph (a)	4,000	4,080
147	Schedule 9, clause 4, item 2, paragraph (b)	5,680	5,800
148	Schedule 9, clause 4, item 2, paragraph (c)	8,750	8,930
149	Schedule 9, clause 4, item 2, paragraph (d)	14,500	14,800
150	Schedule 9, clause 4, item 2, paragraph (e)	21,500	21,900
151	Schedule 9, clause 4, item 2, paragraph (f)	4,000	4,080
152	Schedule 9, clause 4, item 2, paragraph (g)	6,710	6,850

Amendments relating to fees			
Item	Provision	Omit	Substitute
153	Schedule 9, clause 4, item 2, paragraph (h)	8,750	8,930
154	Schedule 9, clause 4, item 3, paragraphs (d) and (e)	810	830
155	Schedule 9, clause 4, item 3, paragraphs (f), (g) and (h)	1,300	1,330
156	Schedule 9, clause 4, item 4, paragraphs (d), (e) and (f)	4,430	4,520
157	Schedule 9, clause 4, item 5, paragraph (a)	1,620	1,650
158	Schedule 9, clause 4, item 5, paragraph (b)	5,620	5,740
159	Schedule 9, clause 4, item 5, paragraph (c)	8,330	8,500
160	Schedule 9, clause 4, item 5, paragraph (d)	11,400	11,600
161	Schedule 9, clause 4, item 7, paragraph (a)	1,590	1,620
162	Schedule 9, clause 4, item 7, paragraph (b)	8,140	8,310
163	Schedule 9, clause 5, item 1	1,410	1,440
164	Schedule 9, clause 5, item 2	4,780	4,880
165	Schedule 9, clause 5, item 3	7,100	7,250
166	Schedule 9, clause 5, item 4	10,100	10,300
167	Schedule 9, clause 5, item 5	1,410	1,440
168	Schedule 9, clause 5, item 6	740	760
169	Schedule 9, clause 5, item 7	4,040	4,120
170	Schedule 9, clause 5, item 8	790	810
171	Schedule 9, clause 5, item 9	6,310	6,440
172	Schedule 9, clause 5, item 10	810	830
173	Schedule 9, clause 5, item 11	9,330	9,520
174	Schedule 9, clause 5, item 12	540	550
175	Schedule 9, clause 5, item 13	3,120	3,180
176	Schedule 9, clause 5, item 14	1,950	1,990
177	Schedule 9, clause 5, item 15	20,900	21,300
178	Schedule 9, clause 5, item 16	1,950	1,990
179	Schedule 9, clause 5, item 17	20,900	21,300
180	Schedule 9, clause 5, item 18	2,580	2,630
181	Schedule 9, clause 5, item 19	28,300	28,900
182	Schedule 9, clause 5, item 20	2,820	2,880
183	Schedule 9, clause 5, item 21	36,200	36,900
184	Schedule 9, clause 5, item 22	440	450
185	Schedule 9, clause 5, item 23	1,670	1,700
186	Schedule 9, clause 5, item 24	1,790	1,830
187	Schedule 9, clause 5, item 25	13,700	14,000
188	Schedule 9, clause 5, item 26	1,790	1,830
189	Schedule 9, clause 5, item 27	13,700	14,000
190	Schedule 9, clause 5, item 28	1,070	1,090
191	Schedule 9, clause 5, item 29	14,300	14,600
192	Schedule 9, clause 5, item 30	1,070	1,090
193	Schedule 9, clause 5, item 31	14,300	14,600

Schedule 1 Amendments commencing 1 July 2019**Part 1** Fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
194	Schedule 9, clause 5, item 32	2,820	2,880
195	Schedule 9, clause 5, item 33	23,300	23,800
196	Schedule 9, clause 5, item 34	2,820	2,880
197	Schedule 9, clause 5, item 35	23,300	23,800
198	Schedule 9A, Part 2, items 1, 2 and 3	1,090	1,110
199	Schedule 9A, Part 2, item 3A, paragraphs (a) and (b)	420	430
200	Schedule 9A, Part 2, item 4	72,200	73,700
201	Schedule 9A, Part 2, item 5	144,400	147,400
202	Schedule 9A, Part 2, item 6	234,700	239,500
203	Schedule 9A, Part 2, item 7	23,400	23,900
204	Schedule 9A, Part 2, item 8	1,090	1,110
205	Schedule 9A, Part 2, items 8A and 9	6,620	6,760
206	Schedule 9A, Part 2, item 10	17,400	17,800
207	Schedule 9A, Part 2, item 11	34,200	34,900
208	Schedule 9A, Part 2, item 12	21,500	21,900
209	Schedule 9A, Part 2, item 13	16,300	16,600
210	Schedule 9A, Part 2, item 14	670	680
211	Schedule 9A, Part 2, item 16	26,100	26,600
212	Schedule 9A, Part 2, item 17, paragraphs (a) and (b)	360	370

Part 2—Other measures

Therapeutic Goods Regulations 1990

22 Schedule 4 (table item 3, column headed “Therapeutic goods”, paragraph (c))

Repeal the paragraph, substitute:

- (c) the ingredients in the medicine are not of a kind required to be sterile; and
- (ca) the medicine does not contain a substance included in a Schedule to the Poisons Standard; and

23 Schedule 4 (table item 4A, column headed “Therapeutic goods”, paragraph (e))

Repeal the paragraph, substitute:

- (e) the preparation does not contain a substance (other than one that is more than a 1,000-fold dilution of mother tincture) included in a Schedule to the Poisons Standard; and

24 Schedule 4 (table item 8, column headed “Therapeutic goods”, paragraph (c))

Repeal the paragraph, substitute:

- (c) the ingredients in the medicine are not of a kind required to be sterile; and
- (ca) the medicine does not contain a substance included in a Schedule to the Poisons Standard; and

Schedule 1 Amendments commencing 1 July 2019

Part 3 Amendments commencing after Part 3 of Schedule 1 to the Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018

**Part 3—Amendments commencing after Part 3 of Schedule 1
to the Therapeutic Goods Legislation Amendment
(Fees and Other Measures) Regulations 2018**

Therapeutic Goods Regulations 1990

25 Clause 3 of Schedule 9 (table item 6AA, column 3)

Omit “640”, substitute “650”.

26 Clause 3 of Schedule 9 (table item 6ABA, column 3)

Omit “2,430”, substitute “2,480”.