



Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 8 June 2023

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023*.

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. The whole of this instrument	1 July 2023.	1 July 2023

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 After Part 8

Insert:

Part 8A—Waiver and refund of charges

8A.1 Definitions

In this Part:

charge year has the same meaning as in the *Therapeutic Goods (Charges) Regulations 2018*.

transitional medical device means a medical device of a kind mentioned in column 1 of an item in the following table if:

- (a) the medical device was, immediately before 25 November 2021, included in the Register and classified as a class of medical device mentioned in column 2 of the item; or
- (b) on 25 November 2021:
 - (i) the medical device was the subject of a class of application mentioned in column 2 of the item for inclusion in the Register; and
 - (ii) the application had not been finally determined.

Transitional medical device		
Item	Column 1 Kind of medical device	Column 2 Class of medical device or application
1	a medical device of a kind described in subclause 3.4(4B) of Schedule 2	Class IIb
2	a medical device of a kind described in clause 5.10 of Schedule 2	Class I or Class IIa
3	a medical device of a kind described in clause 5.11 of Schedule 2	Class I, Class IIa or Class IIb
4	a medical device of a kind described in subclause 4.2(4) of Schedule 2	Class IIa or Class IIb
5	a medical device of a kind described in subclause 3.2(3A) of Schedule 2	Class IIa or Class IIb

8A.2 Waiver of charges in relation to transitional medical devices

- (1) This subregulation applies in relation to a kind of medical device if, at any time during a charge year:
 - (a) the medical device is a transitional medical device; and
 - (b) the entry for the kind of medical device in the Register does not include any medical device that is not a transitional medical device; and

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- (c) the medical device is included in the Register and classified both as:
 - (i) a class of medical device mentioned in column 2 of an item of the table in the definition of ***transitional medical device*** in regulation 8A.1; and
 - (ii) a class of medical device described in the provision mentioned in column 1 of that item; and
 - (d) the same kind of medical device is also listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, made under the *Private Health Insurance Act 2007*, as in force from time to time.
- (2) The Secretary must, on behalf of the Commonwealth, waive the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the kind of transitional medical device in the Register during the charge year if:
- (a) the person liable to pay the charge applies for the charge to be waived for the charge year; and
 - (b) the application is made in the form (if any) approved, in writing, by the Secretary for the purposes of this subregulation; and
 - (c) the Secretary is reasonably satisfied that subregulation (1) applies in relation to the transitional medical device.

8A.3 Refund of certain charges in relation to transitional medical devices

- (1) This subregulation applies in relation to a kind of medical device if, at any time during a charge year:
- (a) the medical device is a transitional medical device; and
 - (b) the entry for the kind of medical device in the Register does not include any medical device that is not a transitional medical device; and
 - (c) the medical device is included in the Register and classified both as:
 - (i) a class of medical device mentioned in column 2 of an item of the table in the definition of ***transitional medical device*** in regulation 8A.1; and
 - (ii) a class of medical device described in the provision mentioned in column 1 of that item; and
 - (d) the same kind of medical device is also listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, made under the *Private Health Insurance Act 2007*, as in force from time to time; and
 - (e) the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the kind of medical device in the Register during the charge year has been paid.
- (2) The Secretary must, on behalf of the Commonwealth, refund an amount equal to the charge paid if:
- (a) the person who paid the charge applies for the charge to be refunded; and
 - (b) the application is made in the form (if any) approved, in writing, by the Secretary for the purposes of this subregulation; and
 - (c) the Secretary is reasonably satisfied that subregulation (1) applies in relation to the transitional medical device.

2 Before paragraph 10.7(1A)(a)

Insert:

- (aa) a decision to refuse to agree to an application under subregulation 8A.2(2) or 8A.3(2) for a waiver or refund of annual charge;

3 Part 1 of Schedule 5 (table item 1.10A)

Repeal the item, substitute:

1.10A	Conformity assessment—assessment because of changes or proposed changes to an IVD medical device or quality management system applying to that device, under conformity assessment procedures set out in:	Subsections 41LA(1) and (2) of the Act
	(a) Schedule 3, Part 1—Full Quality Management System; or	19,268
	(b) Schedule 3, clause 1.6—Design Examination; or	41,060
	(c) Schedule 3, clause 1.6—Design Examination – Immunohaematology reagent medical devices; or	9,973
	(d) Schedule 3, clause 1.6—Abridged Design Examination – previously registered IVDs; or	2,419
	(e) Schedule 3, Part 2—Type Examination; or	26,533
	(f) Schedule 3, Part 4—Production Quality Management System	16,929
	Note 1: If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable—see item 1.12 and clause 2.1 of this Schedule.	
	Note 2: For an assessment under Schedule 3, Part 2, an additional fee to cover the costs of testing the relevant kind of medical device, or quality management system, is also payable—see clause 2.2 of this Schedule.	

4 Part 1 of Schedule 5 (table items 1.14, 1.14A and 1.14B)

Repeal the items, substitute:

1.14	Application audit assessment, Level 2—for Level 1 activities and review of evidence of conformity for the following kinds of medical device:	Subsections 41LA(3) and (4) of the Act
	(a) Class III medical devices (other than IVD medical devices);	16,000
	(b) all other medical devices (other than IVD medical devices)	4,000

1.14A	Application audit assessment for the following kinds of medical devices:	Subsections 41LA(3) and (4) of the Act	
	(a) Class 1 and Class 2 IVD medical devices;		7,387
	(b) Class 3 IVD medical devices;		22,387
	(c) Class 4 IVD medical devices, other than:		22,387
	(i) Class 4 IVD medical devices that are immunohaematology reagent IVD medical devices; or		
	(ii) devices to which item 1.14B or 1.14C applies;		
	(d) Class 4 IVD medical devices that are immunohaematology reagent IVD medical devices		16,621
1.14B	Application audit assessment for Class 4 in-house IVD medical devices (other than a device to which item 1.14C applies)	Subsections 41LA(3) and (4) of the Act	22,387

5 Paragraph 2.1(b) of Part 2 of Schedule 5

Omit “\$451”, substitute “\$474”.

6 Amendments of listed provisions—Part 1 of Schedule 5

The items of the table in Part 1 of Schedule 5 listed in the following table are amended as set out in the table.

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Item 1.1	1,077	1,416
2	Item 1.4A	4,832	5,083
3	Items 1.4B and 1.4C	2,657	2,795
4	Item 1.4D	78,899	83,002
5	Items 1.4E and 1.4F	56,635	59,580
6	Item 1.5, paragraph (e)	1,098	575
7	Item 1.5A	10,568	11,118
8	Item 1.6A, paragraphs (a) and (b)	164	173
9	Item 1.6A, paragraph (b)	51	54
10	Item 1.6B, paragraphs (a) and (b)	164	173
11	Item 1.6B, paragraph (b)	51	54
12	Item 1.7	19,699	20,723
13	Item 1.7A	5,376	5,656
14	Item 1.8	390	410
14A	Item 1.12	451	474
15	Item 1.13	4,135	4,350
16	Item 1.15, paragraphs (a) and (b)	513	540
17	Item 1.15, paragraph (b)	103	108
18	Item 1.17	1,098	1,155

Therapeutic Goods Regulations 1990

7 Part 2 of Schedule 9 (table items 2A and 2AB)

Repeal the items, substitute:

2A	Fee for varying an entry in the Register (not including evaluation of data) under section 9D (other than subsection 9D(2C)) of the Act, if the variation is for:	
	(a) a registered medicine that is mentioned in Part 1 of Schedule 10—for each submission	1,900
	(b) a listed medicine	474
	(c) a disinfectant	1,400
	(d) a Class 3 or Class 4 IVD medical device that is not covered by paragraph (g)	1,750
	(e) an IVD medical device that is not:	1,000
	(i) a Class 3 or Class 4 IVD medical device; and	
	(ii) covered by paragraph (g)	
	(f) a medical device that is not:	1,000
	(i) an IVD medical device; and	
	(ii) covered by paragraph (g)	
	(g) a medical device, if the following are satisfied:	190 per 10 entries (or part thereof)
	(i) the reason for the variation is that the kind of medical device is <i>affected by the EU transition</i> (within the meaning of subregulation 9.1AA(3) of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>);	
	(ii) the variation only relates to an update to the manufacturer's evidence for the medical device recorded in the entry in the Register for that kind of medical device;	
	(iii) the request is to vary one or more entries in the Register and the manufacturer's evidence to which the update relates is the same for each of the entries	

8 Part 2 of Schedule 9 (table item 9B)

Repeal the item.

9 Amendments of listed provisions

The provisions listed in the following table are amended as set out in the table.

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Paragraph 43AAJ(1)(b)	105,575	111,065
2	Paragraph 43AC(2)(a)	4,309	4,533
3	Paragraph 43AC(2)(b)	7,233	7,609
4	Paragraph 43AC(2)(c)	9,439	9,930
5	Paragraph 43ACA(2)(aa)	1,129	1,188
6	Paragraph 43ACA(2)(ab)	8,208	8,635
7	Paragraph 43ACA(2)(a)	4,350	4,576
8	Paragraph 43ACA(2)(b)	6,813	7,167

Amendments relating to fees			
Item	Provision	Omit	Substitute
9	Paragraph 43ACA(2)(c)	10,065	10,588
10	Paragraph 45(6)(a)	1,180	1,241
11	Paragraph 45(6)(b)	4,709	4,954

10 Amendments of listed provisions—clause 3 of Schedule 9

The items of the table in clause 3 of Schedule 9 listed in the following table are amended as set out in the table.

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Item 1A, paragraphs (a) and (b)	513	540
2	Item 1A, paragraph (b)	103	108
3	Item 1, paragraph (a)	1,857	1,954
4	Item 1, paragraph (b)	23,085	24,285
5	Item 1AAA, paragraph (a)	510	537
6	Item 1AAA, paragraph (b)	6,300	6,628
7	Item 1AA	13,441	14,140
8	Item 1AB	4,874	5,127
9	Item 1ABA	8,885	9,347
10	Item 1AC, paragraph (a)	51,710	54,399
11	Item 1AC, paragraph (b)	30,883	32,489
12	Item 1AD, paragraph (a)	269,838	283,870
13	Item 1AD, paragraph (b)	178,011	187,268
14	Item 1AE	30,780	32,381
15	Item 1AF	129,789	136,538
16	Item 1AG	18,571	19,537
17	Item 1B	13,441	14,140
18	Item 2, paragraph (ba)	51,608	54,292
19	Item 2, paragraph (bb)	17,134	18,025
20	Item 2, paragraph (bc)	34,371	36,158
21	Item 2, paragraph (bca)	54,686	57,530
22	Item 2, paragraph (bd)	30,780	32,381
23	Item 2, subparagraph (be)(i)	10,229	10,761
24	Item 2, subparagraph (be)(ii)	6,679	7,026
25	Item 2, subparagraph (bf)(i)	20,623	21,695
26	Item 2, subparagraph (bf)(ii)	13,338	14,032
27	Item 2, paragraph (bfa)	32,524	34,215
28	Item 2, paragraph (bg)	19,904	20,939
29	Item 2, paragraph (bh)	3,252	3,421
30	Item 2, paragraph (bi)	20,110	21,156
31	Item 2, paragraphs (bj) and (bk)	1,180	1,241
32	Item 2, paragraph (c)	4,699	4,943

Schedule 1 Amendments

Amendments relating to fees			
Item	Provision	Omit	Substitute
33	Item 2, paragraph (d)	2,339	2,461
34	Item 2, paragraph (d)	13,646	14,356
35	Item 2AC	1,180	1,241
36	Item 2B	5,889	6,195
37	Item 2C	4,709	4,954
38	Item 2CA	5,889	6,195
39	Items 2CB to 2CE (wherever occurring)	862	907
40	Item 3, paragraph (a)	482	2,200
41	Item 3, paragraph (b)	893	939
42	Item 3AB, paragraphs (a) and (b)	451	474
43	Item 3AB, paragraph (b)	51	54
44	Item 4, paragraph (a)	206,842	217,598
45	Item 4, subparagraphs (aa)(i) and (ii)	69,050	72,641
46	Item 4, subparagraph (aa)(iii)	137,587	144,742
47	Item 4, paragraph (ab)	218,743	230,118
48	Item 4, paragraph (b)	122,710	129,091
49	Item 4, subparagraph (bb)(i)	40,937	43,066
50	Item 4, subparagraph (bb)(i)	26,573	27,955
51	Item 4, subparagraph (bb)(ii)	40,937	43,066
52	Item 4, subparagraph (bb)(ii)	26,573	27,955
53	Item 4, subparagraph (bb)(iii)	81,772	86,024
54	Item 4, subparagraph (bb)(iii)	53,455	56,235
55	Item 4, paragraph (bc)	4,709	4,954
56	Item 4, paragraph (bd)	130,097	136,862
57	Item 4, paragraph (c)	79,002	83,110
58	Item 4, paragraph (d)	12,928	13,600
59	Item 4, paragraph (g)	80,028	84,189
60	Item 4, paragraph (h)	4,709	4,954
61	Item 6AA	687	723
62	Item 6AB	739	777
63	Item 6ABA	2,627	2,764
64	Item 6AC	1,241	1,306
65	Item 6B	3,950	4,155
66	Item 6BA, paragraphs (a) and (b)	164	173
67	Item 6BA, paragraph (b)	51	54
68	Item 6BB, paragraphs (a) and (b)	164	173
69	Item 6BB, paragraph (b)	51	54
70	Item 6C	8,577	9,023
71	Item 6D, paragraph (a)	11,286	11,873
72	Item 6D, paragraph (b)	14,569	15,327
73	Item 6D, paragraph (c)	19,904	20,939

Amendments relating to fees			
Item	Provision	Omit	Substitute
74	Item 6D, paragraph (d)	26,368	27,739
75	Item 6D, paragraph (e)	39,501	41,555
76	Item 6D, paragraph (f)	52,634	55,371
77	Item 6D, paragraph (g)	79,002	83,110
78	Item 7A, paragraph (a)	11,286	11,873
79	Item 7A, subparagraph (b)(i)	11,286	11,873
80	Item 7A, subparagraph (b)(ii)	14,569	15,327
81	Item 7A, subparagraph (b)(iii)	19,904	20,939
82	Item 7A, subparagraph (b)(iv)	26,368	27,739
83	Item 7A, subparagraph (b)(v)	39,501	41,555
84	Item 7A, subparagraph (b)(vi)	52,634	55,371
85	Item 7A, subparagraph (b)(vii)	79,002	83,110
86	Item 7B, paragraph (a)	11,286	11,873
87	Item 7B, subparagraph (b)(i)	11,286	11,873
88	Item 7B, subparagraph (b)(ii)	14,569	15,327
89	Item 7B, subparagraph (b)(iii)	19,904	20,939
90	Item 7B, subparagraph (b)(iv)	26,368	27,739
91	Item 7B, subparagraph (b)(v)	39,501	41,555
92	Item 7B, subparagraph (b)(vi)	52,634	55,371
93	Item 7B, subparagraph (b)(vii)	79,002	83,110
94	Item 7C	1,118	1,176
95	Item 8, paragraph (a)	841	885
96	Item 8, paragraph (b)	1,098	1,155
97	Items 8A to 8C	841	855
98	Item 9, paragraph (a)	1,047	1,101
99	Item 9, paragraph (b)	1,467	1,543
100	Item 9AA	718	755
101	Item 9AB	975	1,026
102	Items 9AC and 9ACA	718	755
103	Item 9AD, paragraph (a)	1,416	1,490
104	Item 9AD, paragraph (b)	12,004	12,628
105	Item 9AD, paragraph (c)	27,086	28,494
106	Item 9AD, paragraph (d)	36,423	38,317
107	Item 9AD, paragraph (e)	56,738	59,688
108	Item 9AD, paragraph (f)	75,616	79,548
109	Item 9AD, paragraph (g)	92,237	97,033
110	Item 10	185	195
111	Item 14, paragraphs (a) and (b)	390	410
112	Item 18	2,380	2,504

11 Amendments of listed provisions—clause 4 of Schedule 9

The items of the table in clause 4 of Schedule 9 listed in the following table are amended as set out in the table.

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Item 1, paragraphs (a) and (b)	1,744	1,835
2	Item 1, paragraph (c)	2,801	2,947
3	Item 1, paragraph (d)	4,094	4,307
4	Item 1, paragraph (e)	6,064	6,379
5	Item 1, paragraphs (f) to (h)	1,744	1,835
6	Item 1, paragraph (i)	2,801	2,947
7	Item 2, paragraph (a)	4,309	4,533
8	Item 2, paragraph (b)	6,125	6,444
9	Item 2, paragraph (c)	9,439	9,930
10	Item 2, paragraph (d)	15,698	16,514
11	Item 2, paragraph (e)	23,085	24,285
12	Item 2, paragraph (f)	4,309	4,533
13	Item 2, paragraph (g)	7,233	7,609
14	Item 2, paragraph (h)	9,439	9,930
15	Item 3, paragraphs (d) and (e)	882	928
16	Item 3, paragraphs (f) to (h)	1,406	1,479
17	Item 4, paragraphs (d) to (f)	4,781	5,030
18	Item 5, paragraph (a)	1,744	1,835
19	Item 5, paragraph (b)	6,064	6,379
20	Item 5, paragraph (c)	8,988	9,455
21	Item 5, paragraph (d)	12,209	12,844
22	Item 7, paragraph (a)	1,713	1,802
23	Item 7, paragraph (b)	8,783	9,240

12 Amendments of listed provisions—clause 5 of Schedule 9

The items of the table in clause 5 of Schedule 9 listed in the following table are amended as set out in the table.

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Item 1A	2,103	2,212
2	Item 1B	9,183	9,661
3	Item 1C	841	885
4	Items 1D and 1E	975	1,026
5	Item 1F	841	885
6	Item 1G	1,129	1,188
7	Item 1H	8,208	8,635
8	Item 1	1,529	1,609

Amendments relating to fees			
Item	Provision	Omit	Substitute
9	Item 2	5,161	5,429
10	Item 3	7,664	8,063
11	Item 4	10,876	11,442
12	Item 5	1,529	1,609
13	Item 6	800	842
14	Item 7	4,350	4,576
15	Item 8	862	907
16	Item 9	6,813	7,167
17	Item 10	882	928
18	Item 11	10,065	10,588
19	Item 12	585	615
20	Item 13	3,355	3,529
21	Item 14	2,103	2,212
22	Item 15	22,469	23,637
23	Item 16	2,103	2,212
24	Item 17	22,469	23,637
25	Item 18	2,780	2,925
26	Item 19	30,575	32,165
27	Item 20	3,047	3,205
28	Item 21	38,988	41,015
29	Item 22	472	497
30	Item 23	1,796	1,889
31	Item 24	1,939	2,040
32	Item 25	14,877	15,651
33	Item 26	1,939	2,040
34	Item 27	14,877	15,651
35	Item 28	1,149	1,209
36	Item 29	15,493	16,299
37	Item 30	1,149	1,209
38	Item 31	15,493	16,299
39	Item 32	3,047	3,205
40	Item 33	25,240	26,552
41	Item 34	3,047	3,205
42	Item 35	25,240	26,552

13 Amendments of listed provisions—Part 2 of Schedule 9A

The items of the table in Part 2 of Schedule 9A listed in the following table are amended as set out in the table.

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Items 1 and 2	1,170	1,231

Schedule 1 Amendments

Amendments relating to fees			
Item	Provision	Omit	Substitute
2	Item 2A	13,971	14,697
3	Item 3	1,170	1,231
4	Item 3A, paragraphs (a) and (b)	451	474
5	Item 3A, paragraph (b)	51	54
6	Item 4, paragraph (a)	81,397	85,630
7	Item 4, paragraph (b)	77,873	81,922
8	Item 5, paragraph (a)	163,197	171,683
9	Item 5, paragraph (b)	155,849	163,953
10	Item 6, paragraph (a)	263,710	277,423
11	Item 6, paragraph (b)	253,217	266,384
12	Item 7	25,342	26,660
13	Item 8	1,170	1,231
14	Items 8A and 9	7,141	7,512
15	Item 10	18,776	19,752
16	Item 11	36,936	38,857
17	Item 11A, paragraphs (a) and (b)	513	540
18	Item 11A, paragraph (b)	103	108
19	Item 12	23,085	24,285
20	Item 13	17,545	18,457
21	Item 14	718	755
22	Item 16	28,112	29,574
23	Item 16AA	7,670	8,069
24	Item 16A, paragraphs (a) and (b)	164	173
25	Item 16A, paragraph (b)	51	54
26	Item 16B, paragraphs (a) and (b)	164	173
27	Item 16B, paragraph (b)	51	54
28	Item 17, paragraphs (a) and (b)	390	410