



Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2025

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 26 June 2025

Sam Mostyn AC
Governor-General

By Her Excellency's Command

Mark Butler
Minister for Health and Ageing

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2025*.

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 2025.	1 July 2025

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subregulation 9.1AA(1)

Omit “\$31”, substitute “\$32”.

2 Subregulation 9.1AA(2) (method statement, step 2)

Omit “\$31”, substitute “\$32”.

3 Paragraph 2.1(b) of Schedule 5

Omit “\$496”, substitute “\$512”.

4 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	1,483	1,530
2	Item 1.1A	11,065	11,419
3	Item 1.2, paragraph (a)	9,733	10,044
4	Item 1.2, paragraph (b)	9,786	10,099
5	Item 1.3, paragraph (a)	59,511	61,415
6	Item 1.3, paragraph (b)	45,869	47,337
7	Item 1.3A, paragraph (a)	33,623	34,699
8	Item 1.3A, paragraph (b)	71,650	73,943
9	Item 1.3A, paragraph (c)	17,402	17,959
10	Item 1.3A, paragraph (d)	4,222	4,357
11	Item 1.3A, paragraph (e)	46,299	47,781
12	Item 1.3A, paragraph (f)	29,541	30,486
13	Item 1.4A	5,322	5,492
14	Items 1.4B and 1.4C	2,926	3,020
15	Item 1.4D	86,903	89,684
16	Items 1.4E and 1.4F	62,380	64,376
17	Item 1.5, paragraph (b)	1,483	1,530
18	Item 1.5, paragraphs (c) and (d)	1,150	1,187
19	Item 1.5, paragraph (e)	602	621
20	Item 1.5, paragraph (f)	96	99
21	Item 1.5, paragraph (g)	602	621
22	Item 1.5, paragraph (h)	1,150	1,187
23	Item 1.5, paragraph (i)	96	99
24	Item 1.5A	11,641	12,014

Amendments relating to fees			
Item	Provision	Omit	Substitute
25	Item 1.6A, paragraphs (a) and (b)	181	187
26	Item 1.6A, paragraph (b)	57	59
27	Item 1.6B, paragraphs (a) and (b)	181	187
28	Item 1.6B, paragraph (b)	57	59
29	Item 1.7	21,697	22,391
30	Item 1.7A	5,922	6,112
31	Item 1.8, paragraphs (a) and (b)	429	443
32	Item 1.9, paragraph (a)	33,516	34,589
33	Item 1.9, paragraph (b)	65,850	61,842
34	Item 1.9, paragraph (c)	45,869	47,337
35	Item 1.9, paragraph (d)	32,119	33,147
36	Item 1.9, paragraph (e)	29,326	30,264
37	Item 1.9, paragraph (f)	25,030	25,831
38	Item 1.9A, paragraph (a)	33,623	34,699
39	Item 1.9A, paragraph (b)	71,650	67,288
40	Item 1.9A, paragraph (c)	17,402	17,959
41	Item 1.9A, paragraph (d)	4,222	4,357
42	Item 1.9A, paragraph (e)	46,299	47,781
43	Item 1.9A, paragraph (f)	29,541	30,486
44	Item 1.10, paragraph (a)	20,196	20,842
45	Item 1.10, paragraph (b)	39,746	37,326
46	Item 1.10, paragraph (c)	27,715	28,602
47	Item 1.10, paragraph (d)	17,402	17,959
48	Item 1.10, paragraph (e)	15,254	15,742
49	Item 1.10A, paragraph (a)	20,174	20,820
50	Item 1.10A, paragraph (b)	42,990	40,373
51	Item 1.10A, paragraph (c)	10,442	10,776
52	Item 1.10A, paragraph (d)	2,533	2,614
53	Item 1.10A, paragraph (e)	27,780	28,669
54	Item 1.10A, paragraph (f)	17,725	18,292
55	Item 1.12	496	512
56	Item 1.13	4,554	4,700
57	Item 1.14, paragraph (a)	16,752	17,288
58	Item 1.14, paragraph (b)	4,188	4,322
59	Item 1.14A, paragraph (a)	7,734	7,981
60	Item 1.14A, paragraphs (b) and (c)	23,439	24,189
61	Item 1.14A, paragraph (d)	17,402	17,959
62	Item 1.14AA	14,865	15,341
63	Item 1.14B	23,439	24,189
64	Item 1.14C	17,402	17,959
65	Item 1.15, paragraphs (a) and (b)	565	583

Schedule 1 Amendments**Part 1** Amendments relating to fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
66	Item 1.15, paragraph (b)	113	117
67	Item 1.17	1,209	1,248

Therapeutic Goods Regulations 1990**5 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)	118,064	121,712
2	Paragraph 43AC(2)(a)	4,746	4,898
3	Paragraph 43AC(2)(b)	7,967	8,222
4	Paragraph 43AC(2)(c)	10,397	10,730
5	Paragraph 43ACA(2)(aa)	1,244	1,284
6	Paragraph 43ACA(2)(ab)	9,041	9,330
7	Paragraph 43ACA(2)(a)	4,791	4,944
8	Paragraph 43ACA(2)(b)	7,504	7,744
9	Paragraph 43ACA(2)(c)	11,086	11,441
10	Paragraph 45(6)(a)	1,299	1,341
11	Paragraph 45(6)(b)	5,187	5,353

6 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)	565	583
2	Item 1A, paragraph (b)	113	117
3	Item 1A, paragraph (c)	3,712	3,831
4	Item 1, paragraph (a)	2,046	2,111
5	Item 1, paragraph (b)	25,426	26,240
6	Item 1AAA, paragraph (a)	562	580
7	Item 1AAA, paragraph(b)	6,940	7,162
8	Item 1AA	14,805	15,279
9	Item 1AB	5,368	5,540
10	Item 1ABA	9,786	10,099
11	Item 1AC, paragraph (a)	56,956	58,779
12	Item 1AC, paragraph (b)	34,016	35,105
13	Item 1AD, paragraph (a)	297,212	306,723
14	Item 1AD, paragraph (b)	196,070	202,344

Amendments relating to fees			
Item	Provision	Omit	Substitute
15	Item 1AE	33,903	34,988
16	Item 1AF	142,955	147,530
17	Item 1AG	20,455	21,110
18	Item 1B	14,805	15,279
19	Item 2, paragraph (ba)	56,844	58,663
20	Item 2, paragraph (bb)	18,872	19,476
21	Item 2, paragraph (bc)	37,857	39,068
22	Item 2, paragraph (bca)	60,234	62,161
23	Item 2, paragraph (bcb)	1,299	1,341
24	Item 2, paragraph (bd)	33,903	34,988
25	Item 2, subparagraph (be)(i)	11,267	11,628
26	Item 2, subparagraph (be)(ii)	7,356	7,591
27	Item 2, subparagraph (bf)(i)	22,715	23,442
28	Item 2, subparagraph (bf)(ii)	14,692	15,162
29	Item 2, paragraph (bfa)	35,823	36,969
30	Item 2, paragraph (bg)	21,923	22,625
31	Item 2, paragraph (bh)	3,582	3,697
32	Item 2, paragraph (bi)	22,150	22,859
33	Item 2, paragraphs (bj) and (bk)	1,299	1,341
34	Item 2, paragraph (c)	5,175	5,341
35	Item 2, paragraph (d)	2,577	2,659
36	Item 2, paragraph (d)	15,031	15,512
37	Item 2A, paragraph (a)	1,989	2,053
38	Item 2A, paragraph (b)	496	512
39	Item 2A, paragraph (c)	1,466	1,513
40	Item 2A, paragraph (d)	1,832	1,891
41	Item 2A, paragraphs (e) and (f)	1,047	1,081
42	Item 2A, paragraph (g)	199	205
43	Item 2AC	1,299	1,341
44	Item 2B	6,486	6,694
45	Item 2C	5,187	5,353
46	Item 2CA	6,486	6,694
47	Items 2CB to 2CE (wherever occurring)	950	980
48	Item 3, paragraph (a)	2,303	2,377
49	Item 3, paragraph (b)	983	1,014
50	Item 3AB, paragraphs (a) and (b)	496	512
51	Item 3AB, paragraph (b)	57	59
52	Item 4, paragraph (a)	227,825	235,115
53	Item 4, subparagraphs (aa)(i) and (ii)	76,055	78,489
54	Item 4, subparagraph (aa)(iii)	151,545	156,394
55	Item 4, paragraph (ab)	240,934	248,644

Schedule 1 Amendments**Part 1** Amendments relating to fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
56	Item 4, paragraph (ac)	5,187	5,353
57	Item 4, paragraph (b)	135,158	139,483
58	Item 4, subparagraph (bb)(i)	45,090	46,533
59	Item 4, subparagraph (bb)(i)	29,269	30,206
60	Item 4, subparagraph (bb)(ii)	45,090	46,533
61	Item 4, subparagraph (bb)(ii)	29,269	30,206
62	Item 4, subparagraph (bb)(iii)	90,067	92,949
63	Item 4, subparagraph (bb)(iii)	58,878	60,762
64	Item 4, paragraph (bc)	5,187	5,353
65	Item 4, paragraph (bd)	143,295	147,880
66	Item 4, paragraph (c)	87,016	89,801
67	Item 4, paragraph (d)	14,239	14,695
68	Item 4, paragraph (g)	88,146	90,967
69	Item 4, paragraph (h)	5,187	5,353
70	Item 6AA	757	781
71	Item 6AB	814	840
72	Item 6ABA	2,894	2,987
73	Item 6AC	1,367	1,411
74	Item 6B	4,350	4,489
75	Item 6BA, paragraphs (a) and (b)	181	187
76	Item 6BA, paragraph (b)	57	59
77	Item 6BB, paragraphs (a) and (b)	181	187
78	Item 6BB, paragraph (b)	57	59
79	Item 6C	9,447	9,749
80	Item 6D, paragraph (a)	12,431	12,829
81	Item 6D, paragraph (b)	16,047	16,561
82	Item 6D, paragraph (c)	21,923	22,625
83	Item 6D, paragraph (d)	29,043	29,972
84	Item 6D, paragraph (e)	43,508	44,900
85	Item 6D, paragraph (f)	57,973	59,828
86	Item 6D, paragraph (g)	87,016	89,801
87	Item 7A, paragraph (a)	12,431	12,829
88	Item 7A, subparagraph (b)(i)	12,431	12,829
89	Item 7A, subparagraph (b)(ii)	16,047	16,561
90	Item 7A, subparagraph (b)(iii)	21,923	22,625
91	Item 7A, subparagraph (b)(iv)	29,043	29,972
92	Item 7A, subparagraph (b)(v)	43,508	44,900
93	Item 7A, subparagraph (b)(vi)	57,973	59,828
94	Item 7A, subparagraph (b)(vii)	87,016	89,801
95	Item 7B, paragraph (a)	12,431	12,829
96	Item 7B, subparagraph (b)(i)	12,431	12,829

Amendments relating to fees			
Item	Provision	Omit	Substitute
97	Item 7B, subparagraph (b)(ii)	16,047	16,561
98	Item 7B, subparagraph (b)(iii)	21,923	22,625
99	Item 7B, subparagraph (b)(iv)	29,043	29,972
100	Item 7B, subparagraph (b)(v)	43,508	44,900
101	Item 7B, subparagraph (b)(vi)	57,973	59,828
102	Item 7B, subparagraph (b)(vii)	87,016	89,801
103	Item 7C	1,231	1,270
104	Item 8, paragraph (a)	927	957
105	Item 8, paragraph (b)	1,209	1,248
106	Items 8A to 8C	927	957
107	Item 9, paragraph (a)	1,153	1,190
108	Item 9, paragraph (b)	1,616	1,668
109	Item 9AA	790	815
110	Item 9AB	1,074	1,108
111	Items 9AC and 9ACA	790	815
112	Item 9AD, paragraph (a)	1,560	1,610
113	Item 9AD, paragraph (b)	13,222	13,645
114	Item 9AD, paragraph (c)	29,833	30,788
115	Item 9AD, paragraph (d)	40,118	41,402
116	Item 9AD, paragraph (e)	62,493	64,493
117	Item 9AD, paragraph (f)	83,287	85,952
118	Item 9AD, paragraph (g)	101,594	104,845
119	Item 10	204	211
120	Item 14, paragraphs (a) and (b)	429	443
121	Item 18	2,622	2,706

7 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)	1,921	1,982
2	Item 1, paragraph (c)	3,086	3,185
3	Item 1, paragraph (d)	4,509	4,653
4	Item 1, paragraph (e)	6,679	6,893
5	Item 1, paragraphs (f) to (h)	1,921	1,982
6	Item 1, paragraph (i)	3,086	3,185
7	Item 2, paragraph (a)	4,746	4,898
8	Item 2, paragraph (b)	6,747	6,963
9	Item 2, paragraph (c)	10,397	10,730
10	Item 2, paragraph (d)	17,290	17,843

Schedule 1 Amendments**Part 1** Amendments relating to fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
11	Item 2, paragraph (e)	25,426	26,240
12	Item 2, paragraph (f)	4,746	4,898
13	Item 2, paragraph (g)	7,967	8,222
14	Item 2, paragraph (h)	10,397	10,730
15	Item 3, paragraphs (d) and (e)	972	1,003
16	Item 3, paragraphs (f) to (h)	1,549	1,599
17	Item 4, paragraphs (d) to (f)	5,266	5,435
18	Item 5, paragraph (a)	1,921	1,982
19	Item 5, paragraph (b)	6,679	6,893
20	Item 5, paragraph (c)	9,899	10,216
21	Item 5, paragraph (d)	13,448	13,878
22	Item 7, paragraph (a)	1,887	1,947
23	Item 7, paragraph (b)	9,674	9,984

8 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	2,316	2,390
2	Item 1B	10,115	10,439
3	Item 1C	927	957
4	Items 1D and 1E	1,074	1,108
5	Item 1F	927	957
6	Item 1G	1,244	1,284
7	Item 1H	9,041	9,330
8	Item 1	1,685	1,739
9	Item 2	5,684	5,866
10	Item 3	8,442	8,712
11	Item 4	11,980	12,363
12	Item 5	1,685	1,739
13	Item 6	882	910
14	Item 7	4,791	4,944
15	Item 8	950	980
16	Item 9	7,504	7,744
17	Item 10	972	1,003
18	Item 11	11,086	11,441
19	Item 12	644	665
20	Item 13	3,695	3,813
21	Item 14	2,316	2,390
22	Item 15	24,748	25,540

Amendments relating to fees			
Item	Provision	Omit	Substitute
23	Item 16	2,316	2,390
24	Item 17	24,748	25,540
25	Item 18	3,062	3,160
26	Item 19	33,677	34,755
27	Item 20	3,356	3,463
28	Item 21	42,943	44,317
29	Item 22	520	537
30	Item 23	1,978	2,041
31	Item 24	2,136	2,204
32	Item 25	16,387	16,911
33	Item 26	2,136	2,204
34	Item 27	16,387	16,911
35	Item 28	1,266	1,307
36	Item 29	17,065	17,611
37	Item 30	1,266	1,307
38	Item 31	17,065	17,611
39	Item 32	3,356	3,463
40	Item 33	27,800	28,690
41	Item 34	3,356	3,463
42	Item 35	27,800	28,690

9 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 to 2AA	1,289	1,330
2	Item 2A	15,388	15,880
3	Item 3	1,289	1,330
4	Item 3A, paragraphs (a) and (b)	496	512
5	Item 3A, paragraph (b)	57	59
6	Item 4, paragraph (a)	89,655	92,524
7	Item 4, paragraph (b)	85,772	88,517
8	Item 5, paragraph (a)	179,752	185,504
9	Item 5, paragraph (b)	171,659	177,152
10	Item 6, paragraph (a)	290,462	299,757
11	Item 6, paragraph (b)	278,904	287,829
12	Item 7	27,913	28,806
13	Item 8	1,289	1,330
14	Items 8A and 9	7,865	8,117
15	Item 10	20,680	21,342

Schedule 1 Amendments**Part 1** Amendments relating to fees

Amendments relating to fees			
Item	Provision	Omit	Substitute
16	Item 11	40,683	41,985
17	Item 11A, paragraphs (a) and (b)	565	583
18	Item 11A, paragraph (b)	113	117
19	Item 12	25,426	26,240
20	Item 13	19,324	19,942
21	Item 14	790	815
22	Item 16	30,964	31,955
23	Item 16AA	\$8,448	8,718
24	Item 16A, paragraphs (a) and (b)	181	187
25	Item 16A, paragraph (b)	57	59
26	Item 16B, paragraphs (a) and (b)	181	187
27	Item 16B, paragraph (b)	57	59
28	Item 17, paragraphs (a) and (b)	429	443

Part 2—Other amendments

Division 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

10 Part 2 of Schedule 4 (at the end of the table)

Add:

- 2.19 Medical device that is:
- (a) a Class 4 in-house IVD medical device; and
 - (b) intended by its manufacturer to be used to detect the presence of, or exposure to, the coronavirus known as severe acute respiratory syndrome coronavirus 2 or SARS-CoV-2 for the purpose of assessing the suitability of a person to donate, for transfusion or transplantation, any of the following of human origin:
 - (i) blood, blood components, blood products, cells, tissues or organs;
 - (ii) any other derivatives of the things covered by subparagraph (i)
- (a) The device must be manufactured only at, or supplied only from, an accredited pathology laboratory (within the meaning of subsection 3(1) of the *Health Insurance Act 1973*).
 - (b) The manufacturer or supplier of the device must:
 - (i) keep records relating to the manufacture, supply or both (as applicable) of the device by the manufacturer or supplier; and
 - (ii) if requested by the Secretary, give a copy of the records to the Secretary.
 - (c) If the manufacture of the device commences on or after 1 July 2025, the device must comply with the essential principles.
 - (d) If the manufacture of the device commences on or after 1 July 2025, the manufacturer of the device must apply the appropriate conformity assessment procedures in relation to the device at all times.
 - (e) The manufacturer of the device must, if requested by the Secretary, provide the following information within 20 working days of receiving the request:
 - (i) if the manufacture of the device commences on or after 1 July 2025—whether the device complies with the essential principles;
 - (ii) if the manufacture of the device commences on or after 1 July 2025—whether the conformity assessment procedures have been applied to the device;
 - (iii) whether the device complies with every applicable requirement (if any) relating to advertising under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.
 - (f) The manufacturer of the device must, at all times, have available:
 - (i) if the manufacture of the device commences on or after 1 July 2025—sufficient information to substantiate that the conformity assessment procedures have been applied to the device; and
 - (ii) information relating to any changes to the device and quality management system.

- (g) The manufacturer or supplier must allow an authorised person to do any of the following:
 - (i) enter, at any reasonable time, any premises at which the device is manufactured or from which the device is supplied (as applicable);
 - (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device;
 - (iii) make any still or moving image or any recording of those premises or anything on those premises.
- (h) If asked to do so by an authorised person, the manufacturer or supplier must produce to the person any documents relating to the device that the person requires and allow the person to copy the documents.
- (i) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.

Division 2—Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

11 In the appropriate position in Part 11

Insert:

Division 11.25—Application provisions relating to the Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2025

11.86 Exempt therapeutic goods

The amendment of Schedule 4 to these Regulations made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2025* applies in relation to therapeutic goods on and after 1 July 2025 regardless of whether the goods were manufactured before, on or after that day.