



# **Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024**

---

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 12 June 2024

David Hurley  
Governor-General

By His Excellency's Command

Mark Butler  
Minister for Health and Aged Care

---



---

## Contents

1	Name .....	1
2	Commencement.....	1
3	Authority .....	1
4	Schedules.....	1
<b>Schedule 1—Amendments commencing 1 July 2024</b>		<b>2</b>
	<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>	2
	<i>Therapeutic Goods Regulations 1990</i>	5
<b>Schedule 2—Amendments commencing 1 January 2025</b>		<b>13</b>
	<i>Therapeutic Goods Regulations 1990</i>	13



---

## 1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024*.

## 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	1 July 2024.	1 July 2024
2. Schedule 1	1 July 2024.	1 July 2024
3. Schedule 2	1 January 2025.	1 January 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 commencing 1 July 2024

### *Therapeutic Goods (Medical Devices) Regulations 2002*

#### **1 Subsection 9.1AA(1)**

Omit “\$30”, substitute “\$31”.

#### **2 Subsection 9.1AA(2) (method statement, step 2)**

Omit “\$30”, substitute “\$31”.

#### **3 Paragraph 9.7(1)(d)**

After “1.14A,”, insert “1.14AA,”.

#### **4 In the appropriate position in Part 11**

Insert:

### **Division 11.21—Application provisions relating to the Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024**

#### **11.77 Application provision—application audit assessment fees**

Table items 1.14A, 1.14AA and 1.14B of Part 1 of Schedule 5 to these Regulations, as amended or inserted by Schedule 1 to the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024*, apply in relation to an application that is made on or after 1 July 2024 and in relation to which an application audit assessment fee is payable because of subsection 41LA(3) of the Act.

#### **5 Part 2 of Schedule 4 (table item 2.3, column headed “Conditions”, paragraph (b))**

Before “item 1.8”, insert “paragraph (a) of”.

#### **6 Part 2 of Schedule 4 (table item 2.3, column headed “Conditions”, after paragraph (h))**

Insert:

(ha) The notification must be accompanied by the notification fee specified in paragraph (b) of item 1.8 of Schedule 5.

#### **7 Part 1 of Schedule 5 (table item 1.4, column headed “Amount (\$)”)**

After “1.14A”, insert “, 1.14AA, 1.14B or 1.14C (as the case may be)”.

#### **8 Part 1 of Schedule 5 (table item 1.8)**

Repeal the item, substitute:

1.8	Each of the following:	Paragraph 63(2)(h) of the Act, and Schedule 4, item 2.3, paragraphs (b)
-----	------------------------	---

	and (ha) of these Regulations	
(a) notification of intention to sponsor a clinical trial of a medical device, including an IVD medical device, to be used solely for experimental purposes in humans, at a trial site;		429
(b) each notification of an additional trial site or additional trial sites for the clinical trial		429

**9 Part 1 of Schedule 5 (at the end of paragraph (b) of table item 1.14A)**

Add “, other than devices to which item 1.14AA applies”.

**10 Part 1 of Schedule 5 (subparagraph (c)(ii) of table item 1.14A)**

After “item”, insert “1.14AA,”.

**11 Part 1 of Schedule 5 (after table item 1.14A)**

Insert:

1.14AA	Application audit assessment for Class 3 IVD medical devices or Class 4 IVD medical devices (other than devices to which paragraph (d) of item 1.14A, or item 1.14C, applies), where the devices are not subject to laboratory testing as part of the auditing of the application	Subsections 41LA(3) and (4) of the Act	14,865
--------	---	--	--------

**12 Part 1 of Schedule 5 (table item 1.14B, column headed “Matter”)**

After “item”, insert “1.14AA or”.

**13 Paragraph 2.1(b) of Schedule 5**

Omit “\$474”, substitute “\$496”.

**14 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.

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
1	Item 1.1	1,416	1,483
2	Item 1.1A	10,568	11,065
3	Item 1.2, paragraph (a)	9,296	9,733
4	Item 1.2, paragraph (b)	9,347	9,786
5	Item 1.3, paragraph (a)	56,840	59,511
6	Item 1.3, paragraph (b)	43,810	45,869
7	Item 1.3A, paragraph (a)	32,114	33,623
8	Item 1.3A, paragraph (b)	68,434	71,650
9	Item 1.3A, paragraph (c)	16,621	17,402

**Schedule 1** Amendments commencing 1 July 2024

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
10	Item 1.3A, paragraph (d)	4,032	4,222
11	Item 1.3A, paragraph (e)	44,221	46,299
12	Item 1.3A, paragraph (f)	28,215	29,541
13	Item 1.4A	5,083	5,322
14	Items 1.4B and 1.4C	2,795	2,926
15	Item 1.4D	83,002	86,903
16	Items 1.4E and 1.4F	59,580	62,380
17	Item 1.5, paragraph (b)	1,416	1,483
18	Item 1.5, paragraphs (c) and (d)	1,098	1,150
19	Item 1.5, paragraph (e)	575	602
20	Item 1.5, paragraph (f)	92	96
21	Item 1.5, paragraph (g)	575	602
22	Item 1.5, paragraph (h)	1,098	1,150
23	Item 1.5, paragraph (i)	92	96
24	Item 1.5A	11,118	11,641
25	Item 1.6A, paragraphs (a) and (b)	173	181
26	Item 1.6A, paragraph (b)	54	57
27	Item 1.6B, paragraphs (a) and (b)	173	181
28	Item 1.6B, paragraph (b)	54	57
29	Item 1.7	20,723	21,697
30	Item 1.7A	5,656	5,922
31	Item 1.9, paragraph (a)	32,011	33,516
32	Item 1.9, paragraph (b)	62,894	65,850
33	Item 1.9, paragraph (c)	43,810	45,869
34	Item 1.9, paragraph (d)	30,677	32,119
35	Item 1.9, paragraph (e)	28,010	29,326
36	Item 1.9, paragraph (f)	23,906	25,030
37	Item 1.9A, paragraph (a)	32,114	33,623
38	Item 1.9A, paragraph (b)	68,434	71,650
39	Item 1.9A, paragraph (c)	16,621	17,402
40	Item 1.9A, paragraph (d)	4,032	4,222
41	Item 1.9A, paragraph (e)	44,221	46,299
42	Item 1.9A, paragraph (f)	28,215	29,541
43	Item 1.10, paragraph (a)	19,289	20,196
44	Item 1.10, paragraph (b)	37,962	39,746
45	Item 1.10, paragraph (c)	26,471	27,715
46	Item 1.10, paragraph (d)	16,621	17,402
47	Item 1.10, paragraph (e)	14,569	15,254
48	Item 1.10A, paragraph (a)	19,268	20,174
49	Item 1.10A, paragraph (b)	41,060	42,990
50	Item 1.10A, paragraph (c)	9,973	10,442



<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
51	Item 1.10A, paragraph (d)	2,419	2,533
52	Item 1.10A, paragraph (e)	26,533	27,780
53	Item 1.10A, paragraph (f)	16,929	17,725
54	Item 1.12	474	496
55	Item 1.13	4,350	4,554
56	Item 1.14, paragraph (a)	16,000	16,752
57	Item 1.14, paragraph (b)	4,000	4,188
58	Item 1.14A, paragraph (a)	7,387	7,734
59	Item 1.14A, paragraphs (b) and (c)	22,387	23,439
60	Item 1.14A, paragraph (d)	16,621	17,402
61	Item 1.14B	22,387	23,439
62	Item 1.14C	16,621	17,402
63	Item 1.15, paragraphs (a) and (b)	540	565
64	Item 1.15, paragraph (b)	108	113
65	Item 1.17	1,155	1,209

### ***Therapeutic Goods Regulations 1990***

#### **15 Clause 3 of Schedule 9 (table item 1A)**

Repeal the item, substitute:

1A	Application fee for processing an application for consent under section 14 or 14A of the Act:	
	(a) for an application relating to goods to which a single entry in the Register relates	565 (for all the goods to which the application relates)
	(b) for an application relating to goods to which both of the following apply:	565 for the first entry plus 113 for each additional entry
	(i) there are separate entries in the Register in relation to the goods;	
	(ii) the way in which the goods do not conform with a standard applicable to the goods is the same for all the goods	
	(c) for an application relating to goods to which no entry in the Register relates	3,712

#### **16 Part 2 of Schedule 9A (table, heading to column headed “Fee”)**

Repeal the heading, substitute:

Fee \$

#### **17 Amendments of listed provisions**

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

**Schedule 1** Amendments commencing 1 July 2024

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
1	Paragraph 43AAJ(1)(b)	\$111,065	\$118,064
2	Paragraph 43AC(2)(a)	\$4,533	\$4,746
3	Paragraph 43AC(2)(b)	\$7,609	\$7,967
4	Paragraph 43AC(2)(c)	\$9,930	\$10,397
5	Paragraph 43ACA(2)(aa)	\$1,188	\$1,244
6	Paragraph 43ACA(2)(ab)	\$8,635	\$9,041
7	Paragraph 43ACA(2)(a)	\$4,576	\$4,791
8	Paragraph 43ACA(2)(b)	\$7,167	\$7,504
9	Paragraph 43ACA(2)(c)	\$10,588	\$11,086
10	Paragraph 45(6)(a)	\$1,241	\$1,299
11	Paragraph 45(6)(b)	\$4,954	\$5,187

**18 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.

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
1	Item 1, paragraph (a)	1,954	2,046
2	Item 1, paragraph (b)	24,285	25,426
3	Item 1AAA, paragraph (a)	537	562
4	Item 1AAA, paragraph (b)	6,628	6,940
5	Item 1AA	14,140	14,805
6	Item 1AB	5,127	5,368
7	Item 1ABA	9,347	9,786
8	Item 1AC, paragraph (a)	54,399	56,956
9	Item 1AC, paragraph (b)	32,489	34,016
10	Item 1AD, paragraph (a)	283,870	297,212
11	Item 1AD, paragraph (b)	187,268	196,070
12	Item 1AE	32,381	33,903
13	Item 1AF	136,538	142,955
14	Item 1AG	19,537	20,455
15	Item 1B	14,140	14,805
16	Item 2, paragraph (ba)	54,292	56,844
17	Item 2, paragraph (bb)	18,025	18,872
18	Item 2, paragraph (bc)	36,158	37,857
19	Item 2, paragraph (bca)	57,530	60,234
20	Item 2, paragraph (bcb)	1,241	1,299
21	Item 2, paragraph (bd)	32,381	33,903
22	Item 2, subparagraph (be)(i)	10,761	11,267
23	Item 2, subparagraph (be)(ii)	7,026	7,356
24	Item 2, subparagraph (bf)(i)	21,695	22,715

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
25	Item 2, subparagraph (bf)(ii)	14,032	14,692
26	Item 2, paragraph (bfa)	34,215	35,823
27	Item 2, paragraph (bg)	20,939	21,923
28	Item 2, paragraph (bh)	3,421	3,582
29	Item 2, paragraph (bi)	21,156	22,150
30	Item 2, paragraphs (bj) and (bk)	1,241	1,299
31	Item 2, paragraph (c)	4,943	5,175
32	Item 2, paragraph (d)	2,461	2,577
33	Item 2, paragraph (d)	14,356	15,031
34	Item 2A, paragraph (a)	1,900	1,989
35	Item 2A, paragraph (b)	474	496
36	Item 2A, paragraph (c)	1,400	1,466
37	Item 2A, paragraph (d)	1,750	1,832
38	Item 2A, paragraphs (e) and (f)	1,000	1,047
39	Item 2A, paragraph (g)	190	199
40	Item 2AC	1,241	1,299
41	Item 2B	6,195	6,486
42	Item 2C	4,954	5,187
43	Item 2CA	6,195	6,486
44	Items 2CB to 2CE (wherever occurring)	907	950
45	Item 3, paragraph (a)	2,200	2,303
46	Item 3, paragraph (b)	939	983
47	Item 3AB, paragraphs (a) and (b)	474	496
48	Item 3AB, paragraph (b)	54	57
49	Item 4, paragraph (a)	217,598	227,825
50	Item 4, subparagraphs (aa)(i) and (ii)	72,641	76,055
51	Item 4, subparagraph (aa)(iii)	144,742	151,545
52	Item 4, paragraph (ab)	230,118	240,934
53	Item 4, paragraph (ac)	4,954	5,187
54	Item 4, paragraph (b)	129,091	135,158
55	Item 4, subparagraph (bb)(i)	43,066	45,090
56	Item 4, subparagraph (bb)(i)	27,955	29,269
57	Item 4, subparagraph (bb)(ii)	43,066	45,090
58	Item 4, subparagraph (bb)(ii)	27,955	29,269
59	Item 4, subparagraph (bb)(iii)	86,024	90,067
60	Item 4, subparagraph (bb)(iii)	56,235	58,878
61	Item 4, paragraph (bc)	4,954	5,187
62	Item 4, paragraph (bd)	136,862	143,295
63	Item 4, paragraph (c)	83,110	87,016
64	Item 4, paragraph (d)	13,600	14,239
65	Item 4, paragraph (g)	84,189	88,146

**Schedule 1** Amendments commencing 1 July 2024

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
66	Item 4, paragraph (h)	4,954	5,187
67	Item 6AA	723	757
68	Item 6AB	777	814
69	Item 6ABA	2,764	2,894
70	Item 6AC	1,306	1,367
71	Item 6B	4,155	4,350
72	Item 6BA, paragraphs (a) and (b)	173	181
73	Item 6BA, paragraph (b)	54	57
74	Item 6BB, paragraphs (a) and (b)	173	181
75	Item 6BB, paragraph (b)	54	57
76	Item 6C	9,023	9,447
77	Item 6D, paragraph (a)	11,873	12,431
78	Item 6D, paragraph (b)	15,327	16,047
79	Item 6D, paragraph (c)	20,939	21,923
80	Item 6D, paragraph (d)	27,739	29,043
81	Item 6D, paragraph (e)	41,555	43,508
82	Item 6D, paragraph (f)	55,371	57,973
83	Item 6D, paragraph (g)	83,110	87,016
84	Item 7A, paragraph (a)	11,873	12,431
85	Item 7A, subparagraph (b)(i)	11,873	12,431
86	Item 7A, subparagraph (b)(ii)	15,327	16,047
87	Item 7A, subparagraph (b)(iii)	20,939	21,923
88	Item 7A, subparagraph (b)(iv)	27,739	29,043
89	Item 7A, subparagraph (b)(v)	41,555	43,508
90	Item 7A, subparagraph (b)(vi)	55,371	57,973
91	Item 7A, subparagraph (b)(vii)	83,110	87,016
92	Item 7B, paragraph (a)	11,873	12,431
93	Item 7B, subparagraph (b)(i)	11,873	12,431
94	Item 7B, subparagraph (b)(ii)	15,327	16,047
95	Item 7B, subparagraph (b)(iii)	20,939	21,923
96	Item 7B, subparagraph (b)(iv)	27,739	29,043
97	Item 7B, subparagraph (b)(v)	41,555	43,508
98	Item 7B, subparagraph (b)(vi)	55,371	57,973
99	Item 7B, subparagraph (b)(vii)	83,110	87,016
100	Item 7C	1,176	1,231
101	Item 8, paragraph (a)	885	927
102	Item 8, paragraph (b)	1,155	1,209
103	Items 8A to 8C	855	927
104	Item 9, paragraph (a)	1,101	1,153
105	Item 9, paragraph (b)	1,543	1,616
106	Item 9AA	755	790

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
107	Item 9AB	1,026	1,074
108	Items 9AC and 9ACA	755	790
109	Item 9AD, paragraph (a)	1,490	1,560
110	Item 9AD, paragraph (b)	12,628	13,222
111	Item 9AD, paragraph (c)	28,494	29,833
112	Item 9AD, paragraph (d)	38,317	40,118
113	Item 9AD, paragraph (e)	59,688	62,493
114	Item 9AD, paragraph (f)	79,548	83,287
115	Item 9AD, paragraph (g)	97,033	101,594
116	Item 10	195	204
117	Item 14, paragraphs (a) and (b)	410	429
118	Item 18	2,504	2,622

### **19 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.

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
1	Item 1, paragraphs (a) and (b)	1,835	1,921
2	Item 1, paragraph (c)	2,947	3,086
3	Item 1, paragraph (d)	4,307	4,509
4	Item 1, paragraph (e)	6,379	6,679
5	Item 1, paragraphs (f) to (h)	1,835	1,921
6	Item 1, paragraph (i)	2,947	3,086
7	Item 2, paragraph (a)	4,533	4,746
8	Item 2, paragraph (b)	6,444	6,747
9	Item 2, paragraph (c)	9,930	10,397
10	Item 2, paragraph (d)	16,514	17,290
11	Item 2, paragraph (e)	24,285	25,426
12	Item 2, paragraph (f)	4,533	4,746
13	Item 2, paragraph (g)	7,609	7,967
14	Item 2, paragraph (h)	9,930	10,397
15	Item 3, paragraphs (d) and (e)	928	972
16	Item 3, paragraphs (f) to (h)	1,479	1,549
17	Item 4, paragraphs (d) to (f)	5,030	5,266
18	Item 5, paragraph (a)	1,835	1,921
19	Item 5, paragraph (b)	6,379	6,679
20	Item 5, paragraph (c)	9,455	9,899
21	Item 5, paragraph (d)	12,844	13,448
22	Item 7, paragraph (a)	1,802	1,887

**Schedule 1** Amendments commencing 1 July 2024

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
23	Item 7, paragraph (b)	9,240	9,674

**20 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.

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
1	Item 1A	2,212	2,316
2	Item 1B	9,661	10,115
3	Item 1C	885	927
4	Items 1D and 1E	1,026	1,074
5	Item 1F	885	927
6	Item 1G	1,188	1,244
7	Item 1H	8,635	9,041
8	Item 1	1,609	1,685
9	Item 2	5,429	5,684
10	Item 3	8,063	8,442
11	Item 4	11,442	11,980
12	Item 5	1,609	1,685
13	Item 6	842	882
14	Item 7	4,576	4,791
15	Item 8	907	950
16	Item 9	7,167	7,504
17	Item 10	928	972
18	Item 11	10,588	11,086
19	Item 12	615	644
20	Item 13	3,529	3,695
21	Item 14	2,212	2,316
22	Item 15	23,637	24,748
23	Item 16	2,212	2,316
24	Item 17	23,637	24,748
25	Item 18	2,925	3,062
26	Item 19	32,165	33,677
27	Item 20	3,205	3,356
28	Item 21	41,015	42,943
29	Item 22	497	520
30	Item 23	1,889	1,978
31	Item 24	2,040	2,136
32	Item 25	15,651	16,387
33	Item 26	2,040	2,136
34	Item 27	15,651	16,387

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
35	Item 28	1,209	1,266
36	Item 29	16,299	17,065
37	Item 30	1,209	1,266
38	Item 31	16,299	17,065
39	Item 32	3,205	3,356
40	Item 33	26,552	27,800
41	Item 34	3,205	3,356
42	Item 35	26,552	27,800

## **21 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.

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
1	Items 1 to 2AA	\$1,231	1,289
2	Item 2A	\$14,697	15,388
3	Item 3	\$1,231	1,289
4	Item 3A, paragraphs (a) and (b)	\$474	496
5	Item 3A, paragraph (b)	\$54	57
6	Item 4, paragraph (a)	\$85,630	89,655
7	Item 4, paragraph (b)	\$81,922	85,772
8	Item 5, paragraph (a)	\$171,683	179,752
9	Item 5, paragraph (b)	\$163,953	171,659
10	Item 6, paragraph (a)	\$277,423	290,462
11	Item 6, paragraph (b)	\$266,384	278,904
12	Item 7	\$26,660	27,913
13	Item 8	\$1,231	1,289
14	Items 8A and 9	\$7,512	7,865
15	Item 10	\$19,752	20,680
16	Item 11	\$38,857	40,683
17	Item 11A, paragraphs (a) and (b)	\$540	565
18	Item 11A, paragraph (b)	\$108	113
19	Item 12	\$24,285	25,426
20	Item 13	\$18,457	19,324
21	Item 14	\$755	790
22	Item 16	\$29,574	30,964
23	Item 16AA	\$8,069	\$8,448
24	Item 16A, paragraphs (a) and (b)	\$173	181
25	Item 16A, paragraph (b)	\$54	57
26	Item 16B, paragraphs (a) and (b)	\$173	181
27	Item 16B, paragraph (b)	\$54	57

**Schedule 1** Amendments commencing 1 July 2024

---

---

<b>Amendments relating to fees</b>			
<b>Item</b>	<b>Provision</b>	<b>Omit</b>	<b>Substitute</b>
28	Item 17, paragraphs (a) and (b)	\$410	429

---



---

## Schedule 2—Amendments commencing 1 January 2025

### *Therapeutic Goods Regulations 1990*

#### **1 Clause 3 of Schedule 9 (after table item 1AF)**

Insert:

1AFA	Fee for the purposes of subsection 28(3A) of the Act for a request under that subsection:	
	(a) if the request relates to therapeutic goods that are specified in Part 1 of Schedule 10 to these Regulations	2,879
	(b) if the request relates to any other therapeutic goods not covered by paragraph (a) of this item	1,790

#### **2 Part 2 of Schedule 9A (after table item 2A)**

Insert:

2B	Fee for the purposes of subsection 32EE(2) of the Act for a request under that subsection.	2,010
----	--	-------