



Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020

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 11 June 2020

David Hurley
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 2020*.

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 2020.	1 July 2020

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 Amendments of listed provisions

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Schedule 5, Part 1, item 1.1	1,020	1,040
2	Schedule 5, Part 1, item 1.1A	10,000	10,200
3	Schedule 5, Part 1, item 1.2, paragraph (a)	8,800	8,970
4	Schedule 5, Part 1, item 1.2, paragraph (b)	8,850	9,020
5	Schedule 5, Part 1, item 1.3, paragraph (a)	53,800	54,800
6	Schedule 5, Part 1, item 1.3, paragraph (b)	41,500	42,300
7	Schedule 5, Part 1, item 1.3A, paragraph (a)	30,400	31,000
8	Schedule 5, Part 1, item 1.3A, paragraph (b)	64,700	66,000
9	Schedule 5, Part 1, item 1.3A, paragraph (c)	15,700	16,000
10	Schedule 5, Part 1, item 1.3A, paragraph (d)	3,820	3,890
11	Schedule 5, Part 1, item 1.3A, paragraph (e)	41,900	42,700
12	Schedule 5, Part 1, item 1.3A, paragraph (f)	26,700	27,200
13	Schedule 5, Part 1, item 1.4A	4,570	4,660
14	Schedule 5, Part 1, items 1.4B and 1.4C	2,510	2,560
15	Schedule 5, Part 1, item 1.4D	74,600	76,100
16	Schedule 5, Part 1, items 1.4E and 1.4F	53,600	54,600
17	Schedule 5, Part 1, item 1.5, paragraphs (a) and (b)	1,340	1,370
18	Schedule 5, Part 1, item 1.5, paragraphs (c), (d) and (e)	1,040	1,060
19	Schedule 5, Part 1, item 1.5, paragraph (g)	540	550
20	Schedule 5, Part 1, item 1.5, paragraph (h)	1,040	1,060
21	Schedule 5, Part 1, item 1.5A	10,000	10,200
22	Schedule 5, Part 1, item 1.7	18,600	19,000
23	Schedule 5, Part 1, item 1.8	370	380
24	Schedule 5, Part 1, item 1.9, paragraph (a)	30,300	30,900
25	Schedule 5, Part 1, item 1.9, paragraph (b)	59,500	60,700
26	Schedule 5, Part 1, item 1.9, paragraph (c)	41,500	42,300
27	Schedule 5, Part 1, item 1.9, paragraph (d)	29,000	29,600
28	Schedule 5, Part 1, item 1.9, paragraph (e)	26,500	27,000
29	Schedule 5, Part 1, item 1.9, paragraph (f)	22,700	23,100
30	Schedule 5, Part 1, item 1.9A, paragraph (a)	30,400	31,000
31	Schedule 5, Part 1, item 1.9A, paragraph (b)	64,700	66,000
32	Schedule 5, Part 1, item 1.9A, paragraph (c)	15,700	16,000
33	Schedule 5, Part 1, item 1.9A, paragraph (d)	3,820	3,890

Amendments relating to fees			
Item	Provision	Omit	Substitute
34	Schedule 5, Part 1, item 1.9A, paragraph (e)	41,900	42,700
35	Schedule 5, Part 1, item 1.9A, paragraph (f)	26,700	27,200
36	Schedule 5, Part 1, item 1.10, paragraph (a)	18,200	18,600
37	Schedule 5, Part 1, item 1.10, paragraph (b)	35,900	36,600
38	Schedule 5, Part 1, item 1.10, paragraph (c)	25,000	25,500
39	Schedule 5, Part 1, item 1.10, paragraph (d)	15,700	16,000
40	Schedule 5, Part 1, item 1.10, paragraph (e)	13,800	14,100
41	Schedule 5, Part 1, item 1.12	430	440
42	Schedule 5, Part 1, item 1.13	3,910	3,990
43	Schedule 5, Part 1, item 1.14	7,170	7,310
44	Schedule 5, Part 1, item 1.14A	6,990	7,130
45	Schedule 5, Part 1, item 1.14B	64,700	66,000
46	Schedule 5, Part 1, item 1.14C	15,700	16,000
47	Schedule 5, Part 1, item 1.17	1,040	1,060
48	Schedule 5, Part 2, paragraph 2.1(b)	430	440

Therapeutic Goods Regulations 1990

2 Amendments of listed provisions

Amendments relating to fees			
Item	Provision	Omit	Substitute
1	Paragraph 43AAJ(1)(b)	99,900	101,800
2	Paragraph 43AC(2)(a)	4,080	4,160
3	Paragraph 43AC(2)(b)	6,850	6,980
4	Paragraph 43AC(2)(c)	8,930	9,100
5	Paragraph 43ACA(2)(aa)	1,070	1,090
6	Paragraph 43ACA(2)(ab)	7,770	7,920
7	Paragraph 43ACA(2)(a)	4,120	4,200
8	Paragraph 43ACA(2)(b)	6,440	6,570
9	Paragraph 43ACA(2)(c)	9,520	9,710
10	Paragraph 45(6)(a)	1,120	1,140
11	Paragraph 45(6)(b)	4,450	4,540
12	Schedule 9, clause 3, item 1, paragraph (a)	1,760	1,790
13	Schedule 9, clause 3, item 1, paragraph (b)	21,900	22,300
14	Schedule 9, clause 3, item 1AA	12,800	13,000
15	Schedule 9, clause 3, item 1AB	4,610	4,700
16	Schedule 9, clause 3, item 1AC, paragraph (a)	48,900	49,900
17	Schedule 9, clause 3, item 1AC, paragraph (b)	29,200	29,800
18	Schedule 9, clause 3, item 1AD, paragraph (a)	255,300	260,300

Schedule 1 Amendments**Part 1 Fees**

Amendments relating to fees			
Item	Provision	Omit	Substitute
19	Schedule 9, clause 3, item 1AD, paragraph (b)	168,400	171,700
20	Schedule 9, clause 3, item 1AE	29,100	29,700
21	Schedule 9, clause 3, item 1AF	122,800	125,200
22	Schedule 9, clause 3, item 1AG	17,600	17,900
23	Schedule 9, clause 3, item 1B	12,800	13,000
24	Schedule 9, clause 3, item 2, paragraph (ba)	48,800	49,800
25	Schedule 9, clause 3, item 2, paragraph (bb)	16,200	16,500
26	Schedule 9, clause 3, item 2, paragraph (bc)	32,600	33,200
27	Schedule 9, clause 3, item 2, paragraph (bca)	51,700	52,700
28	Schedule 9, clause 3, item 2, paragraph (bd)	29,100	29,700
29	Schedule 9, clause 3, item 2, subparagraph (be)(i)	9,680	9,870
30	Schedule 9, clause 3, item 2, subparagraph (be)(ii)	6,320	6,440
31	Schedule 9, clause 3, item 2, subparagraph (bf)(i)	19,500	19,900
32	Schedule 9, clause 3, item 2, subparagraph (bf)(ii)	12,700	12,900
33	Schedule 9, clause 3, item 2, paragraph (bfa)	30,800	31,400
34	Schedule 9, clause 3, item 2, paragraph (bg)	18,800	19,200
35	Schedule 9, clause 3, item 2, paragraph (bh)	3,080	3,140
36	Schedule 9, clause 3, item 2, paragraph (bi)	19,000	19,400
37	Schedule 9, clause 3, item 2, paragraphs (bj) and (bk)	1,120	1,140
38	Schedule 9, clause 3, item 2, paragraph (c)	4,440	4,530
39	Schedule 9, clause 3, item 2, paragraph (d)	2,220	2,260
40	Schedule 9, clause 3, item 2, paragraph (d)	12,900	13,200
41	Schedule 9, clause 3, item 2AB	440	450
42	Schedule 9, clause 3, item 2AC	1,120	1,140
43	Schedule 9, clause 3, item 2B	5,570	5,680
44	Schedule 9, clause 3, item 2C	4,450	4,540
45	Schedule 9, clause 3, item 2CA	5,570	5,680
46	Schedule 9, clause 3, items 2CB, 2CC and 2CD	810	830
47	Schedule 9, clause 3, item 2CE, paragraphs (a) and (b)	810	830
48	Schedule 9, clause 3, item 3, paragraph (a)	460	470
49	Schedule 9, clause 3, item 3, paragraph (b)	840	860
50	Schedule 9, clause 3, item 3AB, paragraphs (a) and (b)	430	440
51	Schedule 9, clause 3, item 4, paragraph (a)	195,700	199,500
52	Schedule 9, clause 3, item 4, subparagraphs (aa)(i) and (ii)	65,300	66,600
53	Schedule 9, clause 3, item 4, subparagraph (aa)(iii)	130,200	132,700
54	Schedule 9, clause 3, item 4, paragraph (ab)	207,000	211,000
55	Schedule 9, clause 3, item 4, paragraph (b)	116,100	118,400
56	Schedule 9, clause 3, item 4, subparagraph (bb)(i)	38,700	39,500
57	Schedule 9, clause 3, item 4, subparagraph (bb)(i)	25,100	25,600
58	Schedule 9, clause 3, item 4, subparagraph (bb)(ii)	38,700	39,500
59	Schedule 9, clause 3, item 4, subparagraph (bb)(ii)	25,100	25,600

Amendments relating to fees			
Item	Provision	Omit	Substitute
60	Schedule 9, clause 3, item 4, subparagraph (bb)(iii)	77,400	78,900
61	Schedule 9, clause 3, item 4, subparagraph (bb)(iii)	50,600	51,600
62	Schedule 9, clause 3, item 4, paragraph (bc)	4,450	4,540
63	Schedule 9, clause 3, item 4, paragraph (bd)	123,100	125,500
64	Schedule 9, clause 3, item 4, paragraph (c)	74,700	76,200
65	Schedule 9, clause 3, item 4, paragraph (d)	12,300	12,500
66	Schedule 9, clause 3, item 4, paragraph (g)	75,700	77,200
67	Schedule 9, clause 3, item 4, paragraph (h)	4,450	4,540
68	Schedule 9, clause 3, item 6AA	650	660
69	Schedule 9, clause 3, item 6AB	700	710
70	Schedule 9, clause 3, item 6ABA	2,480	2,530
71	Schedule 9, clause 3, item 6AC	1,180	1,200
72	Schedule 9, clause 3, item 6B	3,740	3,810
73	Schedule 9, clause 3, item 6C	8,110	8,270
74	Schedule 9, clause 3, item 6D, paragraph (a)	10,700	10,900
75	Schedule 9, clause 3, item 6D, paragraph (b)	13,800	14,100
76	Schedule 9, clause 3, item 6D, paragraph (c)	18,800	19,200
77	Schedule 9, clause 3, item 6D, paragraph (d)	24,900	25,400
78	Schedule 9, clause 3, item 6D, paragraph (e)	37,400	38,100
79	Schedule 9, clause 3, item 6D, paragraph (f)	49,800	50,800
80	Schedule 9, clause 3, item 6D, paragraph (g)	74,700	76,200
81	Schedule 9, clause 3, item 7A, paragraph (a)	10,700	10,900
82	Schedule 9, clause 3, item 7A, subparagraph (b)(i)	10,700	10,900
83	Schedule 9, clause 3, item 7A, subparagraph (b)(ii)	13,800	14,100
84	Schedule 9, clause 3, item 7A, subparagraph (b)(iii)	18,800	19,200
85	Schedule 9, clause 3, item 7A, subparagraph (b)(iv)	24,900	25,400
86	Schedule 9, clause 3, item 7A, subparagraph (b)(v)	37,400	38,100
87	Schedule 9, clause 3, item 7A, subparagraph (b)(vi)	49,800	50,800
88	Schedule 9, clause 3, item 7A, subparagraph (b)(vii)	74,700	76,200
89	Schedule 9, clause 3, item 7B, paragraph (a)	10,700	10,900
90	Schedule 9, clause 3, item 7B, subparagraph (b)(i)	10,700	10,900
91	Schedule 9, clause 3, item 7B, subparagraph (b)(ii)	13,800	14,100
92	Schedule 9, clause 3, item 7B, subparagraph (b)(iii)	18,800	19,200
93	Schedule 9, clause 3, item 7B, subparagraph (b)(iv)	24,900	25,400
94	Schedule 9, clause 3, item 7B, subparagraph (b)(v)	37,400	38,100
95	Schedule 9, clause 3, item 7B, subparagraph (b)(vi)	49,800	50,800
96	Schedule 9, clause 3, item 7B, subparagraph (b)(vii)	74,700	76,200
97	Schedule 9, clause 3, item 7C	1,060	1,080
98	Schedule 9, clause 3, item 8, paragraph (a)	790	810
99	Schedule 9, clause 3, item 8, paragraph (b)	1,040	1,060
100	Schedule 9, clause 3, items 8A, 8B and 8C	790	810

Schedule 1 Amendments**Part 1 Fees**

Amendments relating to fees			
Item	Provision	Omit	Substitute
101	Schedule 9, clause 3, item 9, paragraph (a)	990	1,010
102	Schedule 9, clause 3, item 9, paragraph (b)	1,390	1,420
103	Schedule 9, clause 3, item 9AA	680	690
104	Schedule 9, clause 3, item 9AB	920	940
105	Schedule 9, clause 3, items 9AC and 9ACA	680	690
106	Schedule 9, clause 3, item 9AD, paragraph (a)	1,340	1,370
107	Schedule 9, clause 3, item 9AD, paragraph (b)	11,400	11,600
108	Schedule 9, clause 3, item 9AD, paragraph (c)	25,600	26,100
109	Schedule 9, clause 3, item 9AD, paragraph (d)	34,400	35,100
110	Schedule 9, clause 3, item 9AD, paragraph (e)	53,700	54,700
111	Schedule 9, clause 3, item 9AD, paragraph (f)	71,500	72,900
112	Schedule 9, clause 3, item 9AD, paragraph (g)	87,300	89,000
113	Schedule 9, clause 3, item 14, paragraphs (a) and (b)	370	380
114	Schedule 9, clause 3, item 17, subparagraph (a)(i)	260	270
115	Schedule 9, clause 3, item 17, subparagraph (a)(ii)	310	320
116	Schedule 9, clause 3, item 17, subparagraph (a)(iii)	480	490
117	Schedule 9, clause 3, item 17A, subparagraph (a)(i)	1,210	1,230
118	Schedule 9, clause 3, item 17A, subparagraph (a)(ii)	640	650
119	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(iii)(A)	920	940
120	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(iii)(B)	260	270
121	Schedule 9, clause 3, item 17A, subparagraph (a)(iv)	450	460
122	Schedule 9, clause 3, item 17A, subparagraph (a)(v)	320	330
123	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(vi)(A)	260	270
124	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(vi)(B)	310	320
125	Schedule 9, clause 3, item 17A, sub-subparagraph (a)(vi)(C)	480	490
126	Schedule 9, clause 3, item 18	2,260	2,300
127	Schedule 9, clause 4, item 1, paragraphs (a) and (b)	1,650	1,680
128	Schedule 9, clause 4, item 1, paragraph (c)	2,650	2,700
129	Schedule 9, clause 4, item 1, paragraph (d)	3,870	3,950
130	Schedule 9, clause 4, item 1, paragraph (e)	5,740	5,850
131	Schedule 9, clause 4, item 1, paragraphs (f), (g) and (h)	1,650	1,680
132	Schedule 9, clause 4, item 1, paragraph (i)	2,650	2,700
133	Schedule 9, clause 4, item 2, paragraph (a)	4,080	4,160
134	Schedule 9, clause 4, item 2, paragraph (b)	5,800	5,910
135	Schedule 9, clause 4, item 2, paragraph (c)	8,930	9,100
136	Schedule 9, clause 4, item 2, paragraph (d)	14,800	15,100
137	Schedule 9, clause 4, item 2, paragraph (e)	21,900	22,300
138	Schedule 9, clause 4, item 2, paragraph (f)	4,080	4,160
139	Schedule 9, clause 4, item 2, paragraph (g)	6,850	6,980
140	Schedule 9, clause 4, item 2, paragraph (h)	8,930	9,100
141	Schedule 9, clause 4, item 3, paragraphs (d) and (e)	830	850

Amendments relating to fees			
Item	Provision	Omit	Substitute
142	Schedule 9, clause 4, item 3, paragraphs (f), (g) and (h)	1,330	1,360
143	Schedule 9, clause 4, item 4, paragraphs (d), (e) and (f)	4520	4,610
144	Schedule 9, clause 4, item 5, paragraph (a)	1,650	1,680
145	Schedule 9, clause 4, item 5, paragraph (b)	5,740	5,850
146	Schedule 9, clause 4, item 5, paragraph (c)	8,500	8,670
147	Schedule 9, clause 4, item 5, paragraph (d)	11,600	11,800
148	Schedule 9, clause 4, item 7, paragraph (a)	1,620	1,650
149	Schedule 9, clause 4, item 7, paragraph (b)	8,310	8,470
150	Schedule 9, clause 5, item 1A	1,990	2,030
151	Schedule 9, clause 5, item 1B	8,690	8,860
152	Schedule 9, clause 5, item 1C	790	810
153	Schedule 9, clause 5, items 1D and 1E	920	940
154	Schedule 9, clause 5, item 1F	790	810
155	Schedule 9, clause 5, item 1G	1,070	1,090
156	Schedule 9, clause 5, item 1H	7,770	7,920
157	Schedule 9, clause 5, item 1	1,440	1,470
158	Schedule 9, clause 5, item 2	4,880	4,980
159	Schedule 9, clause 5, item 3	7,250	7,390
160	Schedule 9, clause 5, item 4	10,300	10,500
161	Schedule 9, clause 5, item 5	1,440	1,470
162	Schedule 9, clause 5, item 6	760	770
163	Schedule 9, clause 5, item 7	4,120	4,200
164	Schedule 9, clause 5, item 8	810	830
165	Schedule 9, clause 5, item 9	6,440	6,570
166	Schedule 9, clause 5, item 10	830	850
167	Schedule 9, clause 5, item 11	9,520	9,710
168	Schedule 9, clause 5, item 12	550	560
169	Schedule 9, clause 5, item 13	3,180	3,240
170	Schedule 9, clause 5, item 14	1,990	2,030
171	Schedule 9, clause 5, item 15	21,300	21,700
172	Schedule 9, clause 5, item 16	1,990	2,030
173	Schedule 9, clause 5, item 17	21,300	21,700
174	Schedule 9, clause 5, item 18	2,630	2,680
175	Schedule 9, clause 5, item 19	28,900	29,500
176	Schedule 9, clause 5, item 20	2,880	2,940
177	Schedule 9, clause 5, item 21	36,900	37,600
178	Schedule 9, clause 5, item 22	450	460
179	Schedule 9, clause 5, item 23	1,700	1,730
180	Schedule 9, clause 5, item 24	1,830	1,870
181	Schedule 9, clause 5, item 25	14,000	14,300
182	Schedule 9, clause 5, item 26	1,830	1,870

Schedule 1 Amendments**Part 1 Fees**

Amendments relating to fees			
Item	Provision	Omit	Substitute
183	Schedule 9, clause 5, item 27	14,000	14,300
184	Schedule 9, clause 5, item 28	1,090	1,110
185	Schedule 9, clause 5, item 29	14,600	14,900
186	Schedule 9, clause 5, item 30	1,090	1,110
187	Schedule 9, clause 5, item 31	14,600	14,900
188	Schedule 9, clause 5, item 32	2,880	2,940
189	Schedule 9, clause 5, item 33	23,800	24,300
190	Schedule 9, clause 5, item 34	2,880	2,940
191	Schedule 9, clause 5, item 35	23,800	24,300
192	Schedule 9A, Part 2, items 1, 2 and 3	1,110	1,130
193	Schedule 9A, Part 2, item 3A, paragraphs (a) and (b)	430	440
194	Schedule 9A, Part 2, item 4	73,700	75,100
195	Schedule 9A, Part 2, item 5	147,400	150,300
196	Schedule 9A, Part 2, item 6	239,500	244,200
197	Schedule 9A, Part 2, item 7	23,900	24,400
198	Schedule 9A, Part 2, item 8	1,110	1,130
199	Schedule 9A, Part 2, items 8A and 9	6,760	6,890
200	Schedule 9A, Part 2, item 10	17,800	18,100
201	Schedule 9A, Part 2, item 11	34,900	35,600
202	Schedule 9A, Part 2, item 12	21,900	22,300
203	Schedule 9A, Part 2, item 13	16,600	16,900
204	Schedule 9A, Part 2, item 14	680	690
205	Schedule 9A, Part 2, item 16	26,600	27,100
206	Schedule 9A, Part 2, item 17, paragraphs (a) and (b)	370	380

Part 2—Other measures

Therapeutic Goods (Medical Devices) Regulations 2002

3 Part 1 of Schedule 5 (table item 1.15)

Repeal the item, substitute:

- | | | | |
|------|--|---|--|
| 1.15 | Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of a medical device, including an IVD medical device: | Sections 41MA and 41MAA and paragraph 63(2)(h) of the Act | |
| | (a) for an application relating to a medical device to which a single entry in the Register relates; or | | 490 (for all the devices to which the application relates) |
| | (b) for an application relating to medical devices to which both of the following apply: | | 490 for the first entry plus 100 for each additional entry |
| | (i) there are separate entries in the Register in relation to the devices; | | |
| | (ii) the way in which the devices do not comply with essential principles is the same for all the devices | | |

Therapeutic Goods Regulations 1990

4 Regulation 2

Insert:

medicinal cannabis products means therapeutic goods that contain, or are manufactured from, any part of a plant of the genus *Cannabis* (including, for example, the flowers, fruiting tops, seeds, stems and leaves of the plant).

5 Subregulation 45AA(1)

Omit “item 6 or 7 in Part 2 of Schedule 9 or”.

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

Omit “decides not to register the therapeutic device or”.

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

Omit “subsection 25(3) or”.

8 Subparagraph 45AA(4)(c)(iii)

Omit “the therapeutic device is registered or”.

9 Schedule 5A (table item 1A, column 3, subparagraph (a)(ii))

Omit “—supply”, substitute “, give”.

10 Schedule 5A (after table item 1A)

Insert:

- | | | |
|----|--|--|
| 2 | Therapeutic goods that are medicinal cannabis products manufactured in Australia under a licence granted under Part 3-3 of the Act and are held under the direct control of the sponsor, until the goods are:
(a) the subject of a notification under item 3; or
(b) approved for supply in Australia under subsection 19(1) or section 19A of the Act; or
(c) authorised for supply under subsection 19(5) of the Act; or
(d) authorised for supply under rules made under subsection 19(7A) of the Act | (a) the supply of the goods must be in accordance with the relevant notification, approval or authorisation; and
(b) the goods must be kept in a warehouse or a properly secured area under the control of the sponsor; and
(c) the sponsor must:
(i) keep records relating to the source and supply of the goods; and
(ii) if requested by the Secretary, give the records to the Secretary |
| 2A | Therapeutic goods that are medicinal cannabis products manufactured in Australia under a licence granted under Part 3-3 of the Act and are held under the direct control of the sponsor, until a decision is made under section 25 or 26 of the Act about the goods | the sponsor must:
(a) keep records about the source of the goods; and
(b) if requested by the Secretary, give the records to the Secretary; and
(c) have lodged an application under section 23 of the Act for the goods before their manufacture |

11 Schedule 5A (table item 3, column 3, paragraph (b))

Omit “or 14A”.

12 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 | 490 (for all the goods to which the application relates) |
|----|---|--|

(b) for an application relating to goods to which both of the following apply:	490 for the first entry plus 100 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	

13 Clause 3 of Schedule 9 (table item 1, column 2, paragraph (c))

Repeal the paragraph.

14 Clause 3 of Schedule 9 (table item 1, column 3, fee relating to paragraph (c))

Omit “18,600”.

15 Clause 3 of Schedule 9 (table item 1, column 2, paragraph (d))

Repeal the paragraph.

16 Clause 3 of Schedule 9 (table item 1, column 3, fee relating to paragraph (d))

Omit “2,800”.

17 Clause 3 of Schedule 9 (table item 2, column 2, subparagraph (d)(i))

Omit “or are therapeutic devices”.

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

Repeal the paragraph.

19 Clause 3 of Schedule 9 (table item 2, column 3, fee relating to paragraph (g))

Omit “1,490”.

20 Clause 3 of Schedule 9 (table item 2A)

Repeal the item, 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	1,740
	(b) a listed medicine	440
	(c) a medical device	470

21 Clause 3 of Schedule 9 (table item 4, column 2, paragraphs (aa) and (bb))

Omit “or a therapeutic device”.

22 Clause 3 of Schedule 9 (table items 6, 6AD, 7, 9B and 9C)

Repeal the items.

23 Clause 3 of Schedule 9 (table item 9D)

Repeal the item, substitute:

9D	Fee for evaluation, under subsection 9D(1), (2) or (3), subsection 24(1A) or paragraph 26(1)(d) of the Act, of data relating to the device component, to which Chapter 4 of the Act applies, of a medicine (in addition to the fee prescribed in item 4, or in Part 3 of this Schedule, for evaluating the medicine)	The fee applicable, under item 1.9, 1.10, 1.12 or 1.16 (and, if applicable, clause 2.2) of Schedule 5 to the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> , to the kind of work to be undertaken
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24 Clause 3 of Schedule 9 (table item 12, column 3)

Omit “, 5, 6 or 7”, substitute “or 5”.

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

Omit “, 5, 6 or 7”, substitute “or 5”.

26 Clause 3 of Schedule 9 (table item 14A)

Repeal the item.

27 Part 2 of Schedule 9A (after table item 11)

Insert:

11A	Application fee for processing an application for consent under section 14 or 14A of the Act:	
	(a) for an application relating to goods that are biologicals to which a single entry in the Register relates	490 (for all the goods to which the application relates)
	(b) for an application relating to goods that are biologicals to which both of the following apply:	490 for the first entry plus 100 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	