

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 *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*. | 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Note: This table relates only to the provisions of this instrument as originally made.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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 |
| 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 receives the request | Within 120 working days after the Secretary notifies the applicant that the 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) request | 790 |
| 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 |
| 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 |
| 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 |
| 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 |
| 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 | 4520 |
| 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 |
| 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

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”.