



Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014

Select Legislative Instrument No. 62, 2014

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 regulation.

Dated 29 May 2014

Peter Cosgrove
Governor-General

By His Excellency's Command

Fiona Nash
Assistant Minister for Health

OPC60544 - A

Contents

| | | |
|---|--------------------------|---|
| 1 | Name of regulation | 1 |
| 2 | Commencement..... | 1 |
| 3 | Authority | 1 |
| 4 | Schedule(s)..... | 1 |
| Schedule 1—Amendments | | 2 |
| <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> | | 2 |
| <i>Therapeutic Goods Regulations 1990</i> | | 3 |

1 Name of regulation

This regulation is the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014*.

2 Commencement

This regulation commences on 1 July 2014.

3 Authority

This regulation is made under the *Therapeutic Goods Act 1989*.

4 Schedule(s)

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Amendments of listed provisions

| Amendments of fees | | Omit | Substitute |
|--------------------|--|--------|------------|
| Item | Provision | | |
| 1 | Paragraph 9.4(2)(b) | 3 620 | 3 705 |
| 2 | Schedule 5, item 1.1 | 900 | 920 |
| 3 | Schedule 5, item 1.2, paragraph (a) | 7 780 | 7 965 |
| 4 | Schedule 5, item 1.2, paragraph (b) | 7 830 | 8 020 |
| 5 | Schedule 5, item 1.3, paragraph (a) | 47 700 | 48 800 |
| 6 | Schedule 5, item 1.3, paragraph (b) | 36 700 | 37 600 |
| 7 | Schedule 5, item 1.3A, paragraph (a) | 26 900 | 27 500 |
| 8 | Schedule 5, item 1.3A, paragraph (b) | 57 300 | 58 700 |
| 9 | Schedule 5, item 1.3A, paragraph (c) | 14 000 | 14 300 |
| 10 | Schedule 5, item 1.3A, paragraph (d) | 3 380 | 3 460 |
| 11 | Schedule 5, item 1.3A, paragraph (e) | 37 000 | 37 900 |
| 12 | Schedule 5, item 1.3A, paragraph (f) | 23 600 | 24 200 |
| 13 | Schedule 5, item 1.5, paragraphs (a) and (b) | 1 180 | 1 210 |
| 14 | Schedule 5, item 1.5, paragraphs (c) to (f) | 920 | 940 |
| 15 | Schedule 5, item 1.7 | 16 400 | 16 800 |
| 16 | Schedule 5, item 1.8 | 320 | 330 |
| 17 | Schedule 5, item 1.9, paragraph (a) | 26 800 | 27 400 |
| 18 | Schedule 5, item 1.9, paragraph (b) | 52 700 | 54 000 |
| 19 | Schedule 5, item 1.9, paragraph (c) | 36 700 | 37 600 |
| 20 | Schedule 5, item 1.9, paragraph (d) | 25 600 | 26 200 |
| 21 | Schedule 5, item 1.9, paragraph (e) | 23 400 | 24 000 |
| 22 | Schedule 5, item 1.9, paragraph (f) | 20 000 | 20 500 |
| 23 | Schedule 5, item 1.9A, paragraph (a) | 26 900 | 27 500 |
| 24 | Schedule 5, item 1.9A, paragraph (b) | 57 300 | 58 700 |
| 25 | Schedule 5, item 1.9A, paragraph (c) | 14 000 | 14 300 |
| 26 | Schedule 5, item 1.9A, paragraph (d) | 3 380 | 3 460 |

2 *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014* No. 62, 2014

OPC60544 - A

| Amendments of fees | | | |
|---------------------------|--------------------------------------|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| 27 | Schedule 5, item 1.9A, paragraph (e) | 37 000 | 37 900 |
| 28 | Schedule 5, item 1.9A, paragraph (f) | 23 600 | 24 200 |
| 29 | Schedule 5, item 1.10, paragraph (a) | 16 100 | 16 500 |
| 30 | Schedule 5, item 1.10, paragraph (b) | 31 700 | 32 500 |
| 31 | Schedule 5, item 1.10, paragraph (c) | 22 100 | 22 600 |
| 32 | Schedule 5, item 1.10, paragraph (d) | 14 000 | 14 300 |
| 33 | Schedule 5, item 1.10, paragraph (e) | 12 100 | 12 400 |
| 34 | Schedule 5, item 1.12 | 370 | 380 |
| 35 | Schedule 5, item 1.13 | 3 460 | 3 545 |
| 36 | Schedule 5, item 1.14 | 6 350 | 6 500 |
| 37 | Schedule 5, item 1.14A | 6 180 | 6 330 |
| 38 | Schedule 5, item 1.15 | 400 | 410 |
| 39 | Schedule 5, item 1.17 | 920 | 940 |
| 40 | Schedule 5, paragraph 2.1(b) | 370 | 380 |

Therapeutic Goods Regulations 1990

2 Amendments of listed provisions

| Amendments of fees etc. | | | |
|--------------------------------|-------------------------------|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| 1 | Paragraph 43AAJ(1)(b) | 88 400 | 90 500 |
| 2 | Paragraph 45(4A)(a) | 9 860 | 10 095 |
| 3 | Paragraph 45(4A)(b) | 8 200 | 8 395 |
| 4 | Paragraphs 45(4A)(c) and (ca) | 7 930 | 8 120 |
| 5 | Paragraph 45(4A)(d) | 33 000 | 33 800 |
| 6 | Paragraphs 45(4A)(e) and (f) | 7 930 | 8 120 |
| 7 | Paragraphs 45(9)(a) to (e) | 4 930 | 5 050 |
| 8 | Paragraphs 45(11)(a) to (e) | 1 800 | 1 845 |
| 9 | Regulation 45A | 15 000 | 15 500 |
| 10 | Schedule 9, Part 2, item 1A | 420 | 430 |

Schedule 1 Amendments

| Amendments of fees etc. | | | |
|--------------------------------|--|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| 11 | Schedule 9, Part 2, item 1, paragraph (a) | 1 560 | 1 595 |
| 12 | Schedule 9, Part 2, item 1, paragraph (b) | 19 400 | 19 900 |
| 13 | Schedule 9, Part 2, item 1, paragraph (c) | 16 400 | 16 800 |
| 14 | Schedule 9, Part 2, item 1, paragraph (d) | 2 470 | 2 530 |
| 15 | Schedule 9, Part 2, item 2, paragraph (a) | 1 410 | 1 445 |
| 16 | Schedule 9, Part 2, item 2, paragraph (b) | 1 320 | 1 350 |
| 17 | Schedule 9, Part 2, item 2, paragraph (ba) | 43 200 | 44 200 |
| 18 | Schedule 9, Part 2, item 2, paragraph (bb) | 14 400 | 14 700 |
| 19 | Schedule 9, Part 2, item 2, paragraph (bc) | 28 800 | 29 500 |
| 20 | Schedule 9, Part 2, item 2, paragraph (bd) | 25 700 | 26 300 |
| 21 | Schedule 9, Part 2, item 2, subparagraph (be)(i) | 8 570 | 8 775 |
| 22 | Schedule 9, Part 2, item 2, subparagraph (be)(ii) | 5 590 | 5 725 |
| 23 | Schedule 9, Part 2, item 2, subparagraph (bf)(i) | 17 200 | 17 600 |
| 24 | Schedule 9, Part 2, item 2, subparagraph (bf)(ii) | 11 200 | 11 500 |
| 25 | Schedule 9, Part 2, item 2, paragraph (bg) | 16 600 | 17 000 |
| 26 | Schedule 9, Part 2, item 2, paragraph (bh) | 2 720 | 2 785 |
| 27 | Schedule 9, Part 2, item 2, paragraph (bi) | 16 800 | 17 200 |
| 28 | Schedule 9, Part 2, item 2, paragraph (bj) | 990 | 1 015 |
| 29 | Schedule 9, Part 2, item 2, paragraph (c) | 3 930 | 4 025 |
| 30 | Schedule 9, Part 2, item 2, paragraph (d) | 1 970 | 2 015 |
| 31 | Schedule 9, Part 2, item 2, paragraph (d) | 11 400 | 11 700 |
| 32 | Schedule 9, Part 2, item 2, paragraph (f) | 620 | 635 |
| 33 | Schedule 9, Part 2, item 2, paragraph (g) | 1 320 | 1 350 |
| 34 | Schedule 9, Part 2, item 2, paragraph (h) | 660 | 675 |
| 35 | Schedule 9, Part 2, item 2AA | 600 | 615 |
| 36 | Schedule 9, Part 2, item 2A, paragraph (a) | 1 520 | 1 555 |
| 37 | Schedule 9, Part 2, item 2A, paragraph (b) | 1 410 | 1 445 |
| 38 | Schedule 9, Part 2, item 2A, paragraph (c) | 370 | 380 |
| 39 | Schedule 9, Part 2, item 2A, paragraphs (d) | 400 | 410 |

4 *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014* No. 62, 2014

OPC60544 - A

Amendments of fees etc.

| Item | Provision | Omit | Substitute |
|-------------|---|-------------|-------------------|
| | to (g) | | |
| 40 | Schedule 9, Part 2, item 2AB | 380 | 390 |
| 41 | Schedule 9, Part 2, item 2AC | 990 | 1 015 |
| 42 | Schedule 9, Part 2, item 2B | 4 930 | 5 050 |
| 43 | Schedule 9, Part 2, item 2C | 3 940 | 4 035 |
| 44 | Schedule 9, Part 2, item 2CA | 4 930 | 5 050 |
| 45 | Schedule 9, Part 2, item 3, paragraph (a) | 400 | 410 |
| 46 | Schedule 9, Part 2, item 3, paragraph (b) | 740 | 760 |
| 47 | Schedule 9, Part 2, item 3AA | 600 | 615 |
| 48 | Schedule 9, Part 2, item 3AB | 150 | 155 |
| 49 | Schedule 9, Part 2, item 4, paragraph (a) | 173 000 | 177 200 |
| 50 | Schedule 9, Part 2, item 4, subparagraphs (aa)(i) and (ii) | 57 700 | 59 100 |
| 51 | Schedule 9, Part 2, item 4, subparagraph (aa)(iii) | 115 200 | 118 000 |
| 52 | Schedule 9, Part 2, item 4, paragraph (b) | 102 800 | 105 300 |
| 53 | Schedule 9, Part 2, item 4, subparagraph (bb)(i) | 34 300 | 35 100 |
| 54 | Schedule 9, Part 2, item 4, subparagraph (bb)(i) | 22 200 | 22 700 |
| 55 | Schedule 9, Part 2, item 4, subparagraph (bb)(ii) | 34 300 | 35 100 |
| 56 | Schedule 9, Part 2, item 4, subparagraph (bb)(ii) | 22 200 | 22 700 |
| 57 | Schedule 9, Part 2, item 4, subparagraph (bb)(iii) | 68 500 | 70 100 |
| 58 | Schedule 9, Part 2, item 4, subparagraph (bb)(iii) | 44 700 | 45 800 |
| 59 | Schedule 9, Part 2, item 4, paragraph (c) | 66 000 | 67 600 |
| 60 | Schedule 9, Part 2, item 4, paragraph (d) | 10 900 | 11 200 |
| 61 | Schedule 9, Part 2, item 4, paragraph (g) | 66 900 | 68 500 |
| 62 | Schedule 9, Part 2, item 4, paragraph (h) | 3 940 | 4 035 |
| 63 | Schedule 9, Part 2, item 5, paragraph (a) | 9 440 | 9 665 |
| 64 | Schedule 9, Part 2, item 5, | 9 440 | 9 665 |

Schedule 1 Amendments

| Amendments of fees etc. | | | |
|--------------------------------|---|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| | subparagraph (b)(i) | | |
| 65 | Schedule 9, Part 2, item 5, subparagraph (b)(ii) | 12 100 | 12 400 |
| 66 | Schedule 9, Part 2, item 5, subparagraph (b)(iii) | 16 600 | 17 000 |
| 67 | Schedule 9, Part 2, item 5, subparagraph (b)(iv) | 22 000 | 22 500 |
| 68 | Schedule 9, Part 2, item 5, subparagraph (b)(v) | 33 000 | 33 800 |
| 69 | Schedule 9, Part 2, item 5, subparagraph (b)(vi) | 44 000 | 45 100 |
| 70 | Schedule 9, Part 2, item 5, subparagraph (b)(vii) | 66 000 | 67 600 |
| 71 | Schedule 9, Part 2, item 5, paragraph (c) | 3 410 | 3 490 |
| 72 | Schedule 9, Part 2, item 5, subparagraph (d)(i) | 3 410 | 3 490 |
| 73 | Schedule 9, Part 2, item 5, subparagraph (d)(ii) | 12 100 | 12 400 |
| 74 | Schedule 9, Part 2, item 5, subparagraph (d)(iii) | 16 600 | 17 000 |
| 75 | Schedule 9, Part 2, item 5, subparagraph (d)(iv) | 22 000 | 22 500 |
| 76 | Schedule 9, Part 2, item 5, subparagraph (d)(v) | 33 000 | 33 800 |
| 77 | Schedule 9, Part 2, item 5, subparagraph (d)(vi) | 44 000 | 45 100 |
| 78 | Schedule 9, Part 2, item 5, subparagraph (d)(vii) | 66 000 | 67 600 |
| 79 | Schedule 9, Part 2, item 5A, paragraphs (a) to (f) | 4 930 | 5 050 |
| 80 | Schedule 9, Part 2, item 5B | 16 400 | 16 800 |
| 81 | Schedule 9, Part 2, item 6, paragraph (a) | 28 900 | 29 600 |
| 82 | Schedule 9, Part 2, item 6, paragraphs (b), (c) and (ca) | 19 700 | 20 200 |
| 83 | Schedule 9, Part 2, item 6, paragraph (d) | 33 000 | 33 800 |
| 84 | Schedule 9, Part 2, item 6AA | 350 | 360 |

6 *Therapeutic Goods Legislation Amendment (Fees and Other Measures)
Regulation 2014* No. 62, 2014

OPC60544 - A

Amendments of fees etc.

| Item | Provision | Omit | Substitute |
|-------------|--|-------------|-------------------|
| 85 | Schedule 9, Part 2, item 6AB | 620 | 635 |
| 86 | Schedule 9, Part 2, item 6ABA | 1 870 | 1 915 |
| 87 | Schedule 9, Part 2, item 6AC | 1 050 | 1 075 |
| 88 | Schedule 9, Part 2, item 6AD, paragraph (a) | 19 700 | 20 200 |
| 89 | Schedule 9, Part 2, item 6AD, paragraph (b) | 4 930 | 5 050 |
| 90 | Schedule 9, Part 2, item 6A | 1 320 | 1 350 |
| 91 | Schedule 9, Part 2, item 6B | 3 300 | 3 380 |
| 92 | Schedule 9, Part 2, item 6C | 7 180 | 7 350 |
| 93 | Schedule 9, Part 2, item 6D, paragraph (a) | 9 440 | 9 665 |
| 94 | Schedule 9, Part 2, item 6D, paragraph (b) | 12 100 | 12 400 |
| 95 | Schedule 9, Part 2, item 6D, paragraph (c) | 16 600 | 17 000 |
| 96 | Schedule 9, Part 2, item 6D, paragraph (d) | 22 000 | 22 500 |
| 97 | Schedule 9, Part 2, item 6D, paragraph (e) | 33 000 | 33 800 |
| 98 | Schedule 9, Part 2, item 6D, paragraph (f) | 44 000 | 45 100 |
| 99 | Schedule 9, Part 2, item 6D, paragraph (g) | 66 000 | 67 600 |
| 100 | Schedule 9, Part 2, item 7, paragraph (a) | 9 860 | 10 095 |
| 101 | Schedule 9, Part 2, item 7, paragraphs (b), (c) and (ca) | 8 200 | 8 395 |
| 102 | Schedule 9, Part 2, item 7, paragraph (d) | 33 000 | 33 800 |
| 103 | Schedule 9, Part 2, item 7, paragraphs (e) and (f) | 8 200 | 8 395 |
| 104 | Schedule 9, Part 2, item 7A, paragraph (a) | 9 440 | 9 665 |
| 105 | Schedule 9, Part 2, item 7A, subparagraph (b)(i) | 9 440 | 9 665 |
| 106 | Schedule 9, Part 2, item 7A, subparagraph (b)(ii) | 12 100 | 12 400 |
| 107 | Schedule 9, Part 2, item 7A, subparagraph (b)(iii) | 16 600 | 17 000 |
| 108 | Schedule 9, Part 2, item 7A, subparagraph (b)(iv) | 22 000 | 22 500 |
| 109 | Schedule 9, Part 2, item 7A, subparagraph (b)(v) | 33 000 | 33 800 |
| 110 | Schedule 9, Part 2, item 7A, subparagraph (b)(vi) | 44 000 | 45 100 |

Schedule 1 Amendments

| Amendments of fees etc. | | | |
|--------------------------------|---|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| 111 | Schedule 9, Part 2, item 7A, subparagraph (b)(vii) | 66 000 | 67 600 |
| 112 | Schedule 9, Part 2, item 7B, paragraph (a) | 9 440 | 9 665 |
| 113 | Schedule 9, Part 2, item 7B, subparagraph (b)(i) | 9 440 | 9 665 |
| 114 | Schedule 9, Part 2, item 7B, subparagraph (b)(ii) | 12 100 | 12 400 |
| 115 | Schedule 9, Part 2, item 7B, subparagraph (b)(iii) | 16 600 | 17 000 |
| 116 | Schedule 9, Part 2, item 7B, subparagraph (b)(iv) | 22 000 | 22 500 |
| 117 | Schedule 9, Part 2, item 7B, subparagraph (b)(v) | 33 000 | 33 800 |
| 118 | Schedule 9, Part 2, item 7B, subparagraph (b)(vi) | 44 000 | 45 100 |
| 119 | Schedule 9, Part 2, item 7B, subparagraph (b)(vii) | 66 000 | 67 600 |
| 120 | Schedule 9, Part 2, item 8 | 920 | 940 |
| 121 | Schedule 9, Part 2, item 9, paragraph (a) | 600 | 615 |
| 122 | Schedule 9, Part 2, item 9, paragraph (b) | 1 220 | 1 250 |
| 123 | Schedule 9, Part 2, item 9AA | 600 | 615 |
| 124 | Schedule 9, Part 2, item 9AB | 810 | 830 |
| 125 | Schedule 9, Part 2, items 9AC and 9ACA | 600 | 615 |
| 126 | Schedule 9, Part 2, item 9AD, paragraph (a) | 1 180 | 1 210 |
| 127 | Schedule 9, Part 2, item 9AD, paragraph (b) | 10 200 | 10 400 |
| 128 | Schedule 9, Part 2, item 9AD, paragraph (c) | 22 700 | 23 200 |
| 129 | Schedule 9, Part 2, item 9AD, paragraph (d) | 30 500 | 31 200 |
| 130 | Schedule 9, Part 2, item 9AD, paragraph (e) | 47 600 | 48 700 |
| 131 | Schedule 9, Part 2, item 9AD, paragraph (f) | 63 300 | 64 800 |
| 132 | Schedule 9, Part 2, item 9AD, paragraph (g) | 77 100 | 79 000 |
| 133 | Schedule 9, Part 2, items 9B and 9C | 16 400 | 16 800 |
| 134 | Schedule 9, Part 2, item 10 | 150 | 155 |
| 135 | Schedule 9, Part 2, items 14 and 14A | 320 | 330 |
| 136 | Schedule 9, Part 2, item 17, | 220 | 225 |

8 *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014* No. 62, 2014

OPC60544 - A

| Amendments of fees etc. | | | |
|--------------------------------|---|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| | subparagraph (a)(i) | | |
| 137 | Schedule 9, Part 2, item 17, subparagraph (a)(ii) | 270 | 275 |
| 138 | Schedule 9, Part 2, item 17, subparagraph (a)(iii) | 420 | 430 |
| 139 | Schedule 9, Part 2, item 17, subparagraph (a)(iv) | 110 | 115 |
| 140 | Schedule 9, Part 2, item 17, paragraph (b) | 190 | 195 |
| 141 | Schedule 9, Part 2, item 17, paragraph (c) | 110 | 115 |
| 142 | Schedule 9, Part 2, item 17A, subparagraph (a)(i) | 1 080 | 1 105 |
| 143 | Schedule 9, Part 2, item 17A, subparagraph (a)(ii) | 570 | 585 |
| 144 | Schedule 9, Part 2, item 17A, sub-subparagraph (a)(iii)(A) | 810 | 830 |
| 145 | Schedule 9, Part 2, item 17A, sub-subparagraph (a)(iii)(B) | 230 | 235 |
| 146 | Schedule 9, Part 2, item 17A, subparagraph (a)(iv) | 390 | 400 |
| 147 | Schedule 9, Part 2, item 17A, subparagraph (a)(v) | 280 | 285 |
| 148 | Schedule 9, Part 2, item 17A, sub-subparagraph (a)(vi)(A) | 220 | 225 |
| 149 | Schedule 9, Part 2, item 17A, sub-subparagraph (a)(vi)(B) | 270 | 275 |
| 150 | Schedule 9, Part 2, item 17A, sub-subparagraph (a)(vi)(C) | 420 | 430 |
| 151 | Schedule 9, Part 2, item 17A, paragraph (b) | 190 | 195 |
| 152 | Schedule 9, Part 2, item 18 | 1 990 | 2 040 |
| 153 | Schedule 9A, Part 2, items 1, 2 and 3 | 980 | 1 005 |
| 154 | Schedule 9A, Part 2, item 4 | 65 200 | 66 800 |
| 155 | Schedule 9A, Part 2, item 5 | 130 400 | 133 500 |
| 156 | Schedule 9A, Part 2, item 6 | 211 900 | 217 000 |
| 157 | Schedule 9A, Part 2, item 7 | 21 100 | 21 600 |
| 158 | Schedule 9A, Part 2, item 8 | 980 | 1 005 |

Schedule 1 Amendments

| Amendments of fees etc. | | | |
|--------------------------------|------------------------------|-------------|-------------------|
| Item | Provision | Omit | Substitute |
| 159 | Schedule 9A, Part 2, item 9 | 5 980 | 6 125 |
| 160 | Schedule 9A, Part 2, item 10 | 15 700 | 16 100 |
| 161 | Schedule 9A, Part 2, item 11 | 31 000 | 31 700 |
| 162 | Schedule 9A, Part 2, item 12 | 19 400 | 19 900 |
| 163 | Schedule 9A, Part 2, item 13 | 14 700 | 15 100 |
| 164 | Schedule 9A, Part 2, item 14 | 600 | 615 |
| 165 | Schedule 9A, Part 2, item 16 | 23 500 | 24 100 |
| 166 | Schedule 9A, Part 2, item 17 | 310 | 315 |

10 *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014* No. 62, 2014

OPC60544 - A