

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

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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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 |
| --- |
| Item | Provision | Omit | Substitute |
| 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 |
| 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 |
| 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) to (g) | 400 | 410 |
| 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, subparagraph (b)(i) | 9 440 | 9 665 |
| 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 |
| 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 |
| 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, subparagraph (a)(i) | 220 | 225 |
| 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 |
| 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 |