



Therapeutic Goods Amendment Regulations 2010 (No. 3)¹

Select Legislative Instrument 2010 No. 130

I, QUENTIN BRYCE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated 15 June 2010

QUENTIN BRYCE
Governor-General

By Her Excellency's Command

MARK BUTLER
Parliamentary Secretary for Health

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2010 (No. 3)*.

2 Commencement

These Regulations commence on 1 July 2010.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments

(regulation 3)

[1] Regulation 43AAJ, heading

substitute

43AAJ Charges reduced if annual turnover not more than \$78 600

[2] Regulation 45A, heading

substitute

45A Limit on application fees — low value turnover

[3] Further amendments

| <i>Provision</i> | <i>omit each mention of</i> | <i>insert</i> |
|-------------------------|-----------------------------|---------------|
| Paragraph 43AAJ (1) (b) | \$76 800 | \$78 600 |
| Paragraph 45 (4A) (a) | \$8 560 | \$8 770 |

| <i>Provision</i> | <i>omit each mention of</i> | <i>insert</i> |
|--|-----------------------------|---------------|
| Paragraphs 45 (4A) (b) to (ca) | \$7 130 | \$7 300 |
| Paragraph 45 (4A) (d) | \$28 700 | \$29 400 |
| Paragraphs 45 (4A) (e) and (f) | \$7 130 | \$7 300 |
| Paragraphs 45 (9) (a) to (e) | \$4 290 | \$4 390 |
| Paragraphs 45 (11) (a) to (e) | \$1 570 | \$1 610 |
| Schedule 9, Part 2, item 1A | 370 | 380 |
| Schedule 9, Part 2, item 1 | 1 360 | 1 390 |
| Schedule 9, Part 2, item 1 | 16 900 | 17 300 |
| Schedule 9, Part 2, item 1 | 14 300 | 14 600 |
| Schedule 9, Part 2, item 1 | 2 150 | 2 200 |
| Schedule 9, Part 2, item 2, paragraph (a) | 1 230 | 1 260 |
| Schedule 9, Part 2, item 2, paragraph (b) | 1 140 | 1 170 |
| Schedule 9, Part 2, item 2, paragraph (ba) | 7 600 | 7 780 |
| Schedule 9, Part 2, item 2, paragraph (c) | 3 420 | 3 500 |
| Schedule 9, Part 2, item 2, paragraph (d) | 1 710 | 1 750 |
| Schedule 9, Part 2, item 2, paragraph (d) | 9 960 | 10 200 |
| Schedule 9, Part 2, item 2, paragraph (f) | 540 | 550 |
| Schedule 9, Part 2, item 2, paragraph (g) | 1 140 | 1 170 |
| Schedule 9, Part 2, item 2, paragraph (h) | 580 | 590 |
| Schedule 9, Part 2, item 2AA | 520 | 530 |
| Schedule 9, Part 2, item 2A | 1 320 | 1 350 |
| Schedule 9, Part 2, item 2A | 1 230 | 1 260 |
| Schedule 9, Part 2, item 2A | 320 | 330 |
| Schedule 9, Part 2, item 2A | 350 | 360 |
| Schedule 9, Part 2, items 2B and 2C | 4 290 | 4 390 |
| Schedule 9, Part 2, item 3 | 350 | 360 |
| Schedule 9, Part 2, item 3 | 640 | 660 |
| Schedule 9, Part 2, item 3AA | 520 | 530 |

| <i>Provision</i> | <i>omit each mention of</i> | <i>insert</i> |
|---|-----------------------------|---------------|
| Schedule 9, Part 2, item 4 | 187 900 | 192 400 |
| Schedule 9, Part 2, item 4 | 111 700 | 114 400 |
| Schedule 9, Part 2, item 4 | 71 700 | 73 400 |
| Schedule 9, Part 2, item 4 | 11 800 | 12 100 |
| Schedule 9, Part 2, item 4 | 4 290 | 4 390 |
| Schedule 9, Part 2, item 4 | 1 320 | 1 350 |
| Schedule 9, Part 2, item 4 | 72 800 | 74 500 |
| Schedule 9, Part 2, item 4 | 4 290 | 4 390 |
| Schedule 9, Part 2, item 5, paragraph (a) | 8 190 | 8 390 |
| Schedule 9, Part 2, item 5, subparagraph (b) (i) | 8 190 | 8 390 |
| Schedule 9, Part 2, item 5, subparagraph (b) (ii) | 10 500 | 10 800 |
| Schedule 9, Part 2, item 5, subparagraph (b) (iii) | 14 400 | 14 700 |
| Schedule 9, Part 2, item 5, subparagraph (b) (iv) | 19 100 | 19 600 |
| Schedule 9, Part 2, item 5, subparagraph (b) (v) | 28 700 | 29 400 |
| Schedule 9, Part 2, item 5, subparagraph (b) (vi) | 38 300 | 39 200 |
| Schedule 9, Part 2, item 5, subparagraph (b) (vii) | 57 300 | 58 700 |
| Schedule 9, Part 2, item 5, paragraph (c) | 2 960 | 3 030 |
| Schedule 9, Part 2, item 5, subparagraph (d) (i) | 2 960 | 3 030 |
| Schedule 9, Part 2, item 5, subparagraph (d) (ii) | 10 500 | 10 800 |
| Schedule 9, Part 2, item 5, subparagraph (d) (iii) | 14 400 | 14 700 |
| Schedule 9, Part 2, item 5, subparagraph (d) (iv) | 19 100 | 19 600 |

| <i>Provision</i> | <i>omit each mention of</i> | <i>insert</i> |
|--|-----------------------------|---------------|
| Schedule 9, Part 2, item 5, subparagraph (d) (v) | 28 700 | 29 400 |
| Schedule 9, Part 2, item 5, subparagraph (d) (vi) | 38 300 | 39 200 |
| Schedule 9, Part 2, item 5, subparagraph (d) (vii) | 57 300 | 58 700 |
| Schedule 9, Part 2, item 5A | 4 290 | 4 390 |
| Schedule 9, Part 2, item 5B | 14 300 | 14 600 |
| Schedule 9, Part 2, item 6 | 25 100 | 25 700 |
| Schedule 9, Part 2, item 6 | 17 100 | 17 500 |
| Schedule 9, Part 2, item 6 | 28 700 | 29 400 |
| Schedule 9, Part 2, item 6AA | 300 | 310 |
| Schedule 9, Part 2, item 6AB | 540 | 550 |
| Schedule 9, Part 2, item 6ABA | 1 620 | 1 660 |
| Schedule 9, Part 2, item 6AC | 920 | 940 |
| Schedule 9, Part 2, item 6AD | 17 100 | 17 500 |
| Schedule 9, Part 2, item 6AD | 4 290 | 4 390 |
| Schedule 9, Part 2, item 6A | 1 140 | 1 170 |
| Schedule 9, Part 2, item 6B | 2 870 | 2 940 |
| Schedule 9, Part 2, item 6C | 6 240 | 6 390 |
| Schedule 9, Part 2, item 6D | 8 190 | 8 390 |
| Schedule 9, Part 2, item 6D | 10 500 | 10 800 |
| Schedule 9, Part 2, item 6D | 14 400 | 14 700 |
| Schedule 9, Part 2, item 6D | 19 100 | 19 600 |
| Schedule 9, Part 2, item 6D | 28 700 | 29 400 |
| Schedule 9, Part 2, item 6D | 38 300 | 39 200 |
| Schedule 9, Part 2, item 6D | 57 300 | 58 700 |
| Schedule 9, Part 2, item 7, paragraph (a) | 8 560 | 8 770 |
| Schedule 9, Part 2, item 7, paragraphs (b), (c) and (ca) | 7 130 | 7 300 |

| <i>Provision</i> | <i>omit each mention of</i> | <i>insert</i> |
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| Schedule 9, Part 2, item 7, paragraph (d) | 28 700 | 29 400 |
| Schedule 9, Part 2, item 7, paragraphs (e) and (f) | 7 130 | 7 300 |
| Schedule 9, Part 2, item 7A | 8 190 | 8 390 |
| Schedule 9, Part 2, item 7A | 10 500 | 10 800 |
| Schedule 9, Part 2, item 7A | 14 400 | 14 700 |
| Schedule 9, Part 2, item 7A | 19 100 | 19 600 |
| Schedule 9, Part 2, item 7A | 28 700 | 29 400 |
| Schedule 9, Part 2, item 7A | 38 300 | 39 200 |
| Schedule 9, Part 2, item 7A | 57 300 | 58 700 |
| Schedule 9, Part 2, item 7B | 8 190 | 8 390 |
| Schedule 9, Part 2, item 7B | 10 500 | 10 800 |
| Schedule 9, Part 2, item 7B | 14 400 | 14 700 |
| Schedule 9, Part 2, item 7B | 19 100 | 19 600 |
| Schedule 9, Part 2, item 7B | 28 700 | 29 400 |
| Schedule 9, Part 2, item 7B | 38 300 | 39 200 |
| Schedule 9, Part 2, item 7B | 57 300 | 58 700 |
| Schedule 9, Part 2, item 8 | 790 | 810 |
| Schedule 9, Part 2, item 9 | 520 | 530 |
| Schedule 9, Part 2, item 9 | 1 060 | 1 090 |
| Schedule 9, Part 2, item 9AA | 520 | 530 |
| Schedule 9, Part 2, item 9AB | 710 | 730 |
| Schedule 9, Part 2, items 9AC and 9ACA | 520 | 530 |
| Schedule 9, Part 2, item 9AD | 1 030 | 1 050 |
| Schedule 9, Part 2, item 9AD | 8 870 | 9 080 |
| Schedule 9, Part 2, item 9AD | 19 700 | 20 200 |
| Schedule 9, Part 2, item 9AD | 26 500 | 27 100 |
| Schedule 9, Part 2, item 9AD | 41 400 | 42 400 |
| Schedule 9, Part 2, item 9AD | 55 000 | 56 300 |

| <i>Provision</i> | <i>omit each mention of</i> | <i>insert</i> |
|--------------------------------------|-----------------------------|---------------|
| Schedule 9, Part 2, item 9AD | 67 000 | 68 600 |
| Schedule 9, Part 2, items 9B and 9C | 14 300 | 14 600 |
| Schedule 9, Part 2, items 14 and 14A | 270 | 280 |
| Schedule 9, Part 2, item 17 | 230 | 240 |
| Schedule 9, Part 2, item 17 | 370 | 380 |
| Schedule 9, Part 2, item 17A | 940 | 960 |
| Schedule 9, Part 2, item 17A | 490 | 500 |
| Schedule 9, Part 2, item 17A | 710 | 730 |
| Schedule 9, Part 2, item 17A | 340 | 350 |
| Schedule 9, Part 2, item 17A | 240 | 250 |
| Schedule 9, Part 2, item 17A | 230 | 240 |
| Schedule 9, Part 2, item 17A | 370 | 380 |
| Schedule 9, Part 2, item 18 | 1 730 | 1 770 |

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov.au>.