

2001B00245

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# Therapeutic Goods Amendment Regulations 2001 (No. 2)<sup>1</sup>

Statutory Rules 2001 No. /<sup>2</sup>

160

I, WILLIAM PATRICK DEANE, 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 28 JUN 2001 2001

**WILLIAM DEANE**

Governor-General

By His Excellency's Command

**GRANT TAMBLING**  
Parliamentary Secretary to the Minister for Health  
and Aged Care

**1 Name of Regulations**

These Regulations are the *Therapeutic Goods Amendment Regulations 2001 (No. 1)*. Z

**2 Commencement**

These Regulations commence on 1 July 2001.

**3 Amendment of *Therapeutic Goods Regulations 1990***

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

**Schedule 1 Amendments**

(regulation 3)

**[1] Regulation 45A, heading**

*substitute*

**45A Charges reduced if annual turnover is not more than \$61 000**

**[2] Subregulation 45A (1)**

*omit*

\$56,000

*insert*

\$61 000

**[3] Schedule 9, item 2, column 2, paragraph (a)**

*omit*

of Schedule 9

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**[4] Schedule 9, item 9, column 2, paragraph (b)**

*omit*

(a):

*insert*

(a)

**[5] Schedule 9, column 3**

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 1A	240	260
Item 1, paragraph (a)	1,100	1 170
Item 1, paragraph (b)	13,500	14 390
Item 1, paragraph (c)	10 000	10 660
Item 1, paragraph (d)	1 500	1 600
Item 2, paragraph (a)	650	690
Item 2, paragraph (b)	800	850
Item 2, paragraph (ba)	5,000	\$5 330
Item 2, paragraph (c)	2 400	2 560
Item 2, paragraph (d)	1 200	1 280
Item 2, paragraph (d)	\$7 000	\$7 460
Item 2, paragraph (f)	275	290
Item 2, paragraph (g)	800	850
Item 2, paragraph (h)	400	430
Item 2AA	540	580
Item 2A, paragraph (a)	500	530
Item 2A, paragraph (b)	650	690
Item 2A, paragraph (c)	200	210
Item 2A, paragraph (d)	400	430
Item 2A, paragraph (e)	800	850
Item 2A, paragraph (f)	240	260
Item 3, paragraph (a)	240	260

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 3, paragraph (b)	400	430
Item 3AA	270	290
Item 4, subparagraph (a) (i)	5,400	5 760
Item 4, subparagraph (a) (ii)	16,500	17 590
Item 4, subparagraph (a) (iii)	39,500	42 110
Item 4, subparagraph (a) (iv)	72,500	77 290
Item 4, subparagraph (a) (v)	83,000	88 480
Item 4, subparagraph (a) (vi)	88,500	94 340
Item 4, subparagraph (a) (vii)	93,500	99 670
Item 4, subparagraph (b) (i)	3,125	3 330
Item 4, subparagraph (b) (ii)	10,650	11 350
Item 4, subparagraph (b) (iii)	38,500	41 040
Item 4, subparagraph (b) (iv)	57,000	60 760
Item 4, subparagraph (b) (v)	62,500	66 630
Item 4, subparagraph (b) (vi)	67,500	71 960
Item 4, subparagraph (c) (i)	725	770
Item 4, subparagraph (c) (ii)	6,200	6 610
Item 4, subparagraph (c) (iii)	13,750	14 660
Item 4, subparagraph (c) (iv)	18,500	19 720
Item 4, subparagraph (c) (v)	29,000	30 910
Item 4, subparagraph (c) (vi)	38,500	41 040
Item 4, subparagraph (c) (vii)	47,000	50 100
Item 5, paragraph (a)	4,300	4 580
Item 5, subparagraph (b) (i)	4,300	4 580
Item 5, subparagraph (b) (ii)	5,500	5 860
Item 5, subparagraph (b) (iii)	7,500	8 000
Item 5, subparagraph (b) (iv)	10,000	10 660
Item 5, subparagraph (b) (v)	15,000	15 990
Item 5, subparagraph (b) (vi)	20,000	21 320

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 5, subparagraph (b) (vii)	30,000	31 980
Item 5, paragraph (c)	1,550	1 650
Item 5, subparagraph (d) (i)	1,550	1 650
Item 5, subparagraph (d) (ii)	5,500	5 860
Item 5, subparagraph (d) (iii)	7,500	8 000
Item 5, subparagraph (d) (iv)	10,000	10 660
Item 5, subparagraph (d) (v)	15,000	15 990
Item 5, subparagraph (d) (vi)	20,000	21 320
Item 5, subparagraph (d) (vii)	30,000	31 980
Item 5A, paragraphs (a), (b), (c), (d) and (e)	3 000	3 200
Item 5B	10 000	10 660
Item 6, paragraph (a)	17 600	18 760
Item 6, paragraphs (b), (c) and (ca)	12 000	12 790
Item 6, paragraph (d)	20 000	21 320
Item 6AA	165	180
Item 6AB	165	180
Item 6AC, paragraph (a)	12 000	12 790
Item 6AC, paragraph (b)	3 000	3 200
Item 6A	800	850
Item 6B	2 000	2 130
Item 6C	4 000	4 260
Item 7, paragraph (a)	6 000	6 400
Item 7, paragraphs (b), (c) and (ca)	5 000	5 330
Item 7, paragraph (d)	20 000	21 320
Item 7, paragraphs (e) and (f)	5 000	5 330
Item 7A, paragraph (a)	4,300	4 580
Item 7A, subparagraph (b) (i)	4,300	4 580

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 7A, subparagraph (b) (ii)	5,500	5 860
Item 7A, subparagraph (b) (iii)	7,500	8 000
Item 7A, subparagraph (b) (iv)	10,000	10 660
Item 7A, subparagraph (b) (v)	15,000	15 990
Item 7A, subparagraph (b) (vi)	20,000	21 320
Item 7A, subparagraph (b) (vii)	30,000	31 980
Item 7B, paragraph (a)	4,300	4 580
Item 7B, subparagraph (b) (i)	4,300	4 580
Item 7B, subparagraph (b) (ii)	5,500	5 860
Item 7B, subparagraph (b) (iii)	7,500	8 000
Item 7B, subparagraph (b) (iv)	10,000	10 660
Item 7B, subparagraph (b) (v)	15,000	15 990
Item 7B, subparagraph (b) (vi)	20,000	21 320
Item 7B, subparagraph (b) (vii)	30,000	31 980
Item 8	540	580
Item 9, paragraph (a)	355	380
Item 9, paragraph (b)	745	790
Item 9A	5 625	6 000
Item 9AB	500	530
Item 9AC	355	380
Item 9AD, paragraph (a)	725	770
Item 9AD, paragraph (b)	6 200	6 610
Item 9AD, paragraph (c)	13 750	14 660
Item 9AD, paragraph (d)	18 500	19 720
Item 9AD, paragraph (e)	29 000	30 910
Item 9AD, paragraph (f)	38 500	41 040
Item 9AD, paragraph (g)	47 000	50 100
Item 9B	4 000	4 260
Item 14	200	210

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 14A	200	210
Item 15	420	450
Item 17, subparagraph (a) (i)	120	130
Item 17, subparagraph (a) (ii)	150	160
Item 17, subparagraph (a) (iii)	270	290
Item 17, paragraph (b)	100	110

**Notes**

1. These Regulations amend Statutory Rules 1990 No. 394, as amended by 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332, 370 and 430; 1993 No. 141; 1994 Nos. 150, 222 and 364; 1995 Nos. 33, 111, 192, 208, 253, 320 and 328; 1996 Nos. 9, 25 (disallowed by the House of Representatives on 10 September 1996), 131, 200 and 208; 1997 Nos. 162, 398, 399, 400 and 401 (disallowed by the Senate on 31 March 1998); 1998 Nos. 227, 247 and 369; 1999 Nos. 62, 209 and 324; 2000 Nos. 29, 48, 70, 123, 124 and 267.
2. Notified in the *Commonwealth of Australia Gazette* on / 2001.

, and 358;  
2001 No. 159  
29 June