



F.R.L.I.

TRIPLIC

Administering Department
Please include this copy with documents submitted to
Federal Executive Council Secretariat in connection
with the making of this legislation.
ExCo Secretariat:
Please complete this copy by inserting signatures, date of
making and instrument no. and send to:
Legislative Services and Publication Unit
Office of Legislative Drafting
Attorney-General's Department

2004B00178

Therapeutic Goods Amendment Regulations 2004 (No. 3)¹

Statutory Rules 2004 No. ^L2

159

I, PHILIP MICHAEL JEFFERY, 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 24 JUN 2004 2004

PM Jeffery
Governor-General

By His Excellency's Command

TRISH WORTH
Parliamentary Secretary to the Minister for Health and Ageing

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2004 (No. 1)*.

3

2 Commencement

These Regulations commence on 1 July 2004.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments

(regulation 3)

[1] Subparagraph 42ZCAB (1) (a) (i)

substitute

- (i) subsection 22 (5) or section 42C, 42DL, 42DM or 42DP of the Act; or

[2] Regulation 45 — amendment of fees

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Paragraph 45 (4A) (a)	\$7 025;	\$7 240;
Paragraphs 45 (4A) (b), (c) and (ca)	\$5 855;	\$6 040;
Paragraph 45 (4A) (d)	\$23 410;	\$24 200;
Paragraph 45 (4A) (e)	\$5 855;	\$6 040;
Paragraph 45 (4A) (f)	\$5 855.	\$6 040.
Paragraphs 45 (9) (a), (b), (c), (ca) and (d)	\$3 515;	\$3 630;
Paragraph 45 (9) (e)	\$3 515.	\$3 630.

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Paragraphs 45 (11) (a), (b), (c), (ca) and (d)	\$1 285;	\$1 330;
Paragraph 45 (11) (e)	\$1 285.	\$1 330.

[3] Regulation 45A, heading

substitute

45A Charges reduced if annual turnover is not more than \$65 000

[4] Subregulation 45A (1)

omit

\$62 985

insert

\$65 000

[5] Schedule 9, Part 1, subclause 1 (1), before definition of *major variation*

insert

broadcast media has the meaning given by section 42B of the Act.

[6] Schedule 9, Part 1, subclause 1 (1), after definition of *page*

insert

primary site means the principal manufacturing premises in the capital city of each State and Territory where human blood and blood components are manufactured.

regional area means an area in a State or Territory other than the metropolitan area of the capital city of that State or Territory.

regional station means a radio station or television station that delivers radio programs or television programs to persons in a regional area only.

specified media has the meaning given by section 42B of the Act.

[7] Schedule 9, Part 1, subclause 1 (2)

substitute

- (2) For paragraph (a) of item 2A and items 2B and 4 in Part 2, an application for registration, or variation of the registration, of therapeutic goods of a kind mentioned in Part 1 of Schedule 10 is taken to be a **submission**.

[8] Schedule 9, Part 2, item 2B, column 2

omit

medicine

insert

medicine — for each submission

[9] Schedule 9, Part 2, item 4, columns 2 and 3, paragraphs (a) and (b)

substitute

- | | |
|---|---|
| (a) a new chemical entity (other than an entity to which paragraph (aa) applies) | 189 900 |
| (aa) a new chemical entity incorporated as an ancillary medicinal component of a medical device or a therapeutic device if the evaluation of the new chemical entity involves an evaluation of: | |
| (i) documentation setting out the chemistry, quality control and manufacturing of the new chemical entity; or | one-third of the fee specified in paragraph (a) |
| (ii) documentation relating to pre-clinical studies; or | one-third of the fee specified in paragraph (a) |

(iii) documentation mentioned in subparagraphs (i) and (ii)	two-thirds of the fee specified in paragraph (a)
(b) an extension of indications (other than an extension of indications to which paragraph (bb) applies)	112 900
(bb) an extension of indications or a major variation in respect of a medicine incorporated as an ancillary medicinal component of a medical device or a therapeutic device if the evaluation of the medicine involves an evaluation of:	
(i) documentation setting out the chemistry, quality control and manufacturing of the medicine; or	one-third of the fee specified in paragraph (b) or (g) for an evaluation of that nature
(ii) documentation relating to pre-clinical studies; or	one-third of the fee specified in paragraph (b) or (g) for an evaluation of that nature
(iii) documentation mentioned in subparagraphs (i) and (ii)	two-thirds of the fee specified in paragraph (b) or (g) for an evaluation of that nature

[10] Schedule 9, Part 2, item 9, paragraph (a)

omit

items 9AB and 9AC),

insert

items 9AB, 9AC and 9ACA),

[11] Schedule 9, Part 2, item 9AB, column 2

omit

metropolitan site

insert

primary site

[12] Schedule 9, Part 2, item 9AC, column 2

omit

metropolitan site,

insert

primary site,

[13] Schedule 9, Part 2, after item 9AC

insert

9ACA	Fee for inspection (including an inspection for paragraph 58 (3) (b) of the Act) of manufacturing premises or operations for the preparation of human tissues under licence, for each inspector engaged per hour, or part of an hour	430
------	--	-----

[14] Schedule 9, Part 2, item 10, column 3

omit

80

insert

90

[15] Schedule 9, Part 2, item 17*substitute*

- 17 Fee for an application, under regulation 5F, for approval of an advertisement intended to be published in specified media (other than broadcast media):
- | | |
|---|---|
| (a) if the time needed to process the application is an hour or less — for an advertisement: | |
| (i) of not more than 100 words | 140 |
| (ii) of more than 100 words | 180 |
| (iii) of more than 300 words (including an advertorial) | 310 |
| (iv) that is intended for publication in the classified advertisement columns of a newspaper or other publication | 70 |
| (b) if the time needed to process the application is more than an hour | The fee applicable under paragraph (a) plus \$120 for each additional hour or part of an hour |
| (c) if the application is for approval of a minor change to an approved advertisement (other than a change to information of the kind mentioned in paragraph 5C (2) (b), (e) or (f) of these Regulations) and the application is made more than 3 months after the advertisement was approved | 70 |
| (d) if the application is for approval of an advertisement that is identical to an approved advertisement the approval number of which has expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
| (e) if the application is for approval of a variation of an approved advertisement the approval number of which has not expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |

17A	<p>Fee for an application, under regulation 5F, for approval of an advertisement intended to be broadcast in broadcast media:</p> <p>(a) if the time needed to process the application is an hour or less — for an advertisement that is:</p> <p style="padding-left: 20px;">(i) a television or cinema advertisement of not more than 150 seconds, including up to 3 variations of the advertising concept for the same product 800</p> <p style="padding-left: 20px;">(ii) a television advertisement for a retail outlet that is intended to be broadcast on 1 regional station only in that station's regional area 400</p> <p style="padding-left: 20px;">(iii) a television advertorial of more than 150 seconds:</p> <p style="padding-left: 40px;">(A) for the first minute of each script 600</p> <p style="padding-left: 40px;">(B) for each additional minute or part of a minute of each script 150</p> <p style="padding-left: 20px;">(iv) a radio advertisement, including up to 6 variations of the advertising concept for the same product 290</p> <p style="padding-left: 20px;">(v) a radio advertisement that is intended to be broadcast in a regional area only, including up to 6 variations of the advertising concept for the same product 190</p> <p style="padding-left: 20px;">(vi) a still cinema media advertisement (including outdoor media):</p> <p style="padding-left: 40px;">(A) of not more than 100 words 140</p> <p style="padding-left: 40px;">(B) of not more than 300 words 180</p> <p style="padding-left: 40px;">(C) of more than 300 words 310</p> <p>(b) if the time needed to process the application is more than an hour</p>	<p>The fee applicable under paragraph (a) plus \$120 for each additional hour or part of an hour</p>
-----	---	--

- | | |
|---|---|
| (c) if the application is for approval of a minor change to an approved advertisement (other than a change to information of the kind mentioned in paragraph 5C (2) (b), (e) or (f) of these Regulations) and the application is made more than 3 months after the advertisement was approved | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
| (d) if the application is for approval of an advertisement that is identical to an approved advertisement the approval number of which has expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |
| (e) if the application is for approval of a variation of an approved advertisement the approval number of which has not expired under subregulation 5J (3) | 50% of the fee applicable under paragraph (a) and, if applicable, paragraph (b) |

[16] Schedule 9, Part 2 — amendment of fees

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 1A	290	300
Item 1, paragraph (c)	11 700	12 100
Item 1, paragraph (d)	1 760	1 820
Item 2, paragraph (a)	755	780
Item 2, paragraph (b)	930	960
Item 2, paragraph (ba)	5 670;	5 850;
Item 2, paragraph (c)	2 810	2 900
Item 2, paragraph (d)	1 405	1 450
Item 2, paragraph (d)	\$8 190	\$8 440
Item 2, paragraph (f)	325	340
Item 2, paragraph (g)	930	960
Item 2, paragraph (h)	475	490
Item 2AA	645	670

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 2A, paragraph (a)	1 310	1 300
Item 2A, paragraph (b)	755	780
Item 2A, paragraph (c)	230	240
Item 2A, paragraph (d)	475	490
Item 2A, paragraph (e)	930	960
Item 2A, paragraphs (f) and (g)	290	300
Items 2B and 2C	4 300	4 280
Item 3, paragraph (a)	290	300
Item 3, paragraph (b)	475	490
Item 3AA	325	340
Item 4, paragraph (c)	65 000	67 000
Item 4, paragraph (d)	12 100	11 900
Item 4, paragraph (e)	4 400	4 280
Item 4, paragraph (f)	1 350	1 300
Item 4, paragraph (g)	74 650	73 600
Item 4, paragraph (h)	4 300	4 280
Item 5, paragraph (a) and subparagraph (b) (i)	5 030	5 190
Item 5, subparagraph (b) (ii)	6 435	6 640
Item 5, subparagraph (b) (iii)	8 790	9 060
Item 5, subparagraph (b) (iv)	11 700	12 060
Item 5, subparagraph (b) (v)	17 555	18 100
Item 5, subparagraph (b) (vi)	23 410	24 200
Item 5, subparagraph (b) (vii)	35 105	36 200
Item 5, paragraph (c) and subparagraph (d) (i)	1 810	1 870
Item 5, subparagraph (d) (ii)	6 435	6 640
Item 5, subparagraph (d) (iii)	8 790	9 060
Item 5, subparagraph (d) (iv)	11 700	12 100
Item 5, subparagraph (d) (v)	17 555	18 100
Item 5, subparagraph (d) (vi)	23 410	24 200

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 5, subparagraph (d) (vii)	35 105	36 200
Item 5A, paragraphs (a) to (f)	3 515	3 630
Item 5B	11 700	12 100
Item 6, paragraph (a)	20 600	21 300
Item 6, paragraphs (b), (c) and (ca)	14 045	14 500
Item 6, paragraph (d)	23 410	24 200
Item 6AA	240	250
Item 6AB	210	220
Item 6AC	750	780
Item 6AD, paragraph (a)	14 045	14 500
Item 6AD, paragraph (b)	3 515	3 630
Item 6A	930	960
Item 6B	2 345	2 420
Item 6C	4 680	4 830
Item 6D, paragraph (a)	5 030	5 190
Item 6D, paragraph (b)	6 435	6 640
Item 6D, paragraph (c)	8 790	9 060
Item 6D, paragraph (d)	11 700	12 100
Item 6D, paragraph (e)	17 555	18 100
Item 6D, paragraph (f)	23 410	24 200
Item 6D, paragraph (g)	35 105	36 200
Item 7, paragraph (a)	7 025	7 240
Item 7, paragraphs (b), (c) and (ca)	5 855	6 040
Item 7, paragraph (d)	23 410	24 200
Item 7, paragraphs (e) and (f)	5 855	6 040
Item 7A, paragraph (a) and subparagraph (b) (i)	5 030	5 190
Item 7A, subparagraph (b) (ii)	6 435	6 640
Item 7A, subparagraph (b) (iii)	8 790	9 060
Item 7A, subparagraph (b) (iv)	11 700	12 100

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Item 7A, subparagraph (b) (v)	17 555	18 100
Item 7A, subparagraph (b) (vi)	23 410	24 200
Item 7A, subparagraph (b) (vii)	35 105	36 200
Item 7B, paragraph (a) and subparagraph (b) (i)	5 030	5 190
Item 7B, subparagraph (b) (ii)	6 435	6 640
Item 7B, subparagraph (b) (iii)	8 790	9 060
Item 7B, subparagraph (b) (iv)	11 700	12 100
Item 7B, subparagraph (b) (v)	17 555	18 100
Item 7B, subparagraph (b) (vi)	23 410	24 200
Item 7B, subparagraph (b) (vii)	35 105	36 200
Item 8	645	670
Item 9, paragraph (a)	415	430
Item 9, paragraph (b)	870	900
Item 9AB	580	600
Item 9AC	415	430
Item 9AD, paragraph (a)	850	880
Item 9AD, paragraph (b)	7 260	7 490
Item 9AD, paragraph (c)	16 100	16 600
Item 9AD, paragraph (d)	21 655	22 400
Item 9AD, paragraph (e)	33 930	35 000
Item 9AD, paragraph (f)	45 050	46 500
Item 9AD, paragraph (g)	54 995	56 700
Items 9B and 9C	11 700	12 100
Item 18	9 990	10 300

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, 267 and 358; 2001 Nos. 159, 160, 252 and 343; 2002 Nos. 9, 84, 114, 143, 234, 315 and 345; 2003 Nos. 111, 151, 257, 258, 301 and 361; 2004 Nos. 78 and 127.
2. Notified in the *Commonwealth of Australia Gazette* on L 2004.

25 June