



# Therapeutic Goods Amendment Regulations 2011 (No. 2)<sup>1</sup>

**Select Legislative Instrument 2011 No. 102**

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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 16 June 2011

QUENTIN BRYCE  
Governor-General

By Her Excellency's Command

CATHERINE KING  
Parliamentary Secretary for Health and Ageing

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**1 Name of Regulations**

These Regulations are the *Therapeutic Goods Amendment Regulations 2011 (No. 2)*.

**2 Commencement**

These Regulations commence on 1 July 2011.

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

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

**Schedule 1 Amendments**

(regulation 3)

**[1] Regulation 2, definition of *Complementary Medicines Evaluation Committee***

*substitute*

*complementary medicine* means a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use.

*designated active ingredients*, for a complementary medicine, means an active ingredient, or a kind of active ingredient, mentioned in Schedule 14.

**[2] Regulation 2, definition of *Therapeutic Goods Advertising Code***

*substitute*

*Therapeutic Goods Advertising Code* means the code made under section 42BAA of the Act.

**[3] Regulation 2, after definition of *trade name***

*insert*

***traditional use***, for a designated active ingredient, means use of the designated active ingredient that:

- (a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and
- (b) accords with well-established procedures of preparation, application and dosage.

**[4] Regulation 2, note**

*omit*

*medicine* and *poison*

*insert*

*medicine, poison* and *product information*

**[5] Paragraph 3 (3) (e)**

*omit*

(ACT).

*insert*

(ACT);

**[6] After paragraph 3 (3) (e)**

*insert*

- (f) *Medicines, Poisons and Therapeutic Goods Regulation 2008* (ACT).

**[7] After regulation 3**

*insert*

**3AA Unacceptable presentation of therapeutic goods — prescribed class of medicine**

For paragraph 3 (5) (ca) of the Act, a prescribed class of medicine is medicine for supply in Australia that is not:

- (a) a product of a kind mentioned in Part 1 of Schedule 10; or
- (b) a medicine that satisfies the following requirements:
  - (i) the medicine's label does not contain the advisory statement specified by the Minister under subsection 3 (5A) of the Act for the medicine;
  - (ii) the Secretary has given consent, under sections 14 and 14A of the Act, for the medicine to be imported into, exported from or supplied in Australia without the advisory statement mentioned in subparagraph (i);
  - (iii) the medicine complies with the terms of the Secretary's consent mentioned in subparagraph (ii).

**[8] Subregulation 9B (4), definition of *product information***

*omit*

**[9] Subregulation 15 (1)**

*omit*

paragraph 20 (2) (a)

*insert*

paragraphs 19D (3) (c) and (4) (c)

**[10] Subregulation 15A (1)**

*omit*

Of Registered Medicines Regulated By Office of Prescription Medicines

**[11] Subregulation 35B (1)***omit*

25

*insert*

32

**[12] Subregulation 36B (2)***after*

member

*insert*

of the committee

**[13] Subregulation 37B (1)***omit*

12

*insert*

15

**[14] Subregulation 37B (2)***after*

member

*insert*

of the committee

**[15] Subregulation 38B (2)***after*

expertise in

*insert*

at least

**[16] Subregulation 39B (3)**

*after*

experience in

*insert*

at least

**[17] Paragraphs 41C (1) (d), (e) and (f)**

*substitute*

(d) bankruptcy;

(e) failing to comply with the disclosure of interest requirements mentioned in regulation 42.

**[18] Subregulation 42 (6)**

*omit*

pecuniary interest

*insert*

material personal interest (whether pecuniary or not)

**[19] Subparagraph 42C (1) (a) (v)**

*substitute*

(v) the Medical Technology Association of Australia;

**[20] Subparagraph 42C (1) (b) (ii)**

*substitute*

(ii) the Communications Council;

**[21] Paragraph 42C (1) (f)**

*omit*

Australian Publishers Bureau

*insert*

Publishers' Advertising Advisory Bureau

**[22] Subregulations 42N (1) and (3)***omit*

pecuniary interest

*insert*

material personal interest (whether pecuniary or not)

**[23] Subregulation 42T (1)***omit*

8 members

*insert*

9 members

**[24] Paragraph 42T (1) (b)***omit*

2 members

*insert*

3 members

**[25] After subparagraph 42T (1) (b) (ii)***insert*

(iii) the Medical Technology Association of Australia;

**[26] Subregulation 42T (1A)***omit*

must

*insert*may

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**[27] Subregulation 42T (1A)**

*omit*

medical device or other therapeutic goods

*insert*

therapeutic device

**[28] Subregulation 42T (2)**

*omit*

4 members

*insert*

5 members

**[29] Subregulation 42Y (1)**

*omit*

subregulations (2) and (3),

*insert*

subregulation (3),

**[30] Subregulation 42Y (2)**

*omit*

**[31] Subregulations 42ZB (1) and (3)**

*omit*

pecuniary interest

*insert*

material personal interest (whether pecuniary or not)

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**[32] After paragraph 42ZCAI (4) (a)**

*insert*

- (ab) suspend the registration or listing of goods under subsection 29D (1) of the Act;

**[33] Paragraph 42ZCAI (4) (b)**

*omit*

paragraph 30 (2) (e)

*insert*

section 30

**[34] Regulation 43AAJ, heading**

*substitute*

**43AAJ Licensing charge — reduction in certain circumstances**

**[35] After subregulation 43A (2)**

*insert*

- (3) An application fee is taken not to have been payable for an application for the registration of a therapeutic good made in accordance with section 23 of the Act if:
- (a) the application was made during the period:
- (i) beginning on 1 August 1998 and ending on 23 March 2000; or
  - (ii) beginning on 1 July 2003 and ending on the commencement of this subregulation; and
- (b) the following provisions applied to the application:
- (i) paragraph (c) or (d) of item 2 of Part 2 of Schedule 9;
  - (ii) item 4 of Part 2 of Schedule 9; and

- (c) the fee prescribed in paragraph (c) or (d) of item 2 of Part 2 of Schedule 9 for making the application was not paid; and
- (d) the therapeutic good was included in the Register because of the application.

**[36] Regulation 43AA**

*substitute*

**43AA Fee for evaluation — refund in certain circumstances**

If:

- (a) an applicant has paid the whole of the evaluation fee payable under Schedule 9 for an evaluation of an application under subsection 9D (3) of the Act to which regulation 16D applies; and
- (b) the Secretary has notified the applicant of the decision; and
- (c) the notification did not occur within the period specified for the application in subregulation 16D (3);

then 25% of the evaluation fee must be refunded to the applicant.

**[37] Subregulation 46 (3)**

*omit*

**[38] Schedule 9, Part 1, subclause 1 (2)**

*omit*

2B

*insert*

2B, 2C

**[39] Schedule 9, Part 2, item 2, paragraph (ba), columns 2 and 3**

*substitute*

(ba)	for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (a) of item 4	39 800
(bb)	for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (aa) (i) or (ii) of item 4	13 300
(bc)	for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (aa) (iii) of item 4	26 500
(bd)	for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (b) of item 4	23 700
(be)	for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (bb) (i) or (ii) of item 4 for an evaluation of:	
	(i) an extension of indications	7 890
	(ii) a major variation	5 140
(bf)	for an application relating to a medicine in relation to which an evaluation fee is payable under subparagraph (bb) (iii) of item 4 for an evaluation of:	
	(i) an extension of indications	15 800
	(ii) a major variation	10 300
(bg)	for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (c) of item 4	15 200
(bh)	for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (d) of item 4	2 500
(bi)	for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (g) of item 4	15 400

(bj) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (h) of item 4 910

**[40] Schedule 9, Part 2, item 2A**

*omit*

subsection 9D (1), (2) or (3)

*insert*

section 9D

**[41] Schedule 9, Part 2, after item 2AB**

*insert*

2AC Application fee for an application under subsection 9D (3) of the Act to which regulation 16D applies 910

**[42] Schedule 9, Part 2, item 2C**

*omit*

goods

*insert*

goods — for each submission

**[43] Schedule 9, Part 2, item 4**

*omit*

(if paragraph (ba) of item 2 does not apply)

**[44] Schedule 9, Part 2, item 4, paragraph (a)**

*omit*

192 400

*insert*

159 200

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**[45] Schedule 9, Part 2, item 4, subparagraphs (aa) (i) and (ii)**

*omit*

one-third of the fee specified in paragraph (a)

*insert*

53 100

**[46] Schedule 9, Part 2, item 4, subparagraph (aa) (iii)**

*omit*

two-thirds of the fee specified in paragraph (a)

*insert*

106 100

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

*omit*

114 400

*insert*

94 600

**[48] Schedule 9, Part 2, item 4, subparagraphs (bb) (i) and (ii)**

*omit*

one-third of the fee specified in paragraph (b) or (g) for an evaluation of that nature

*insert*

for an evaluation relating to:

(a) an extension of indications — 31 500

(b) a major variation — 20 500

**[49] Schedule 9, Part 2, item 4, subparagraph (bb) (iii)**

*omit*

two-thirds of the fee specified in paragraph (b) or (g) for an evaluation of that nature

*insert*

for an evaluation relating to:

- (a) an extension of indications — 63 100
- (b) a major variation — 41 100

**[50] Schedule 9, Part 2, item 4, paragraph (c)**

*omit*

73 400

*insert*

60 700

**[51] Schedule 9, Part 2, item 4, paragraph (d)**

*omit*

12 100

*insert*

10 000

**[52] Schedule 9, Part 2, item 4, paragraphs (e) and (f)**

*omit*

**[53] Schedule 9, Part 2, item 4, paragraph (g)**

*omit*

74 500

*insert*

61 600

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**[54] Schedule 9, Part 2, item 4, paragraph (h)**

*omit*

4 390

*insert*

3 630

**[55] Schedule 9, Part 2, item 9AC, column 2**

*omit*

other than the primary site,

*insert*

(other than a site to which item 9AB applies),

**[56] Schedule 9, Part 2, item 12**

*after*

Act

*insert*

that is not covered by another item in this Part

**[57] Schedule 10, Part 1, heading**

*substitute*

**Part 1 Evaluation by Office of Medicines  
Authorisation of prescription and other  
medicines**

**[58] Schedule 10, Part 1, item 14**

*substitute*

14 therapeutic goods referred to the Office of Medicines Authorisation of the Therapeutic Goods Administration within the Department for the purpose of evaluation as a prescription medicine

**[59] Schedule 10, Part 3, heading***substitute***Part 3 Evaluation by Office of Medicines  
Authorisation of non-prescription and  
other medicines****[60] Schedule 10, Part 3, item 5***substitute*

5 therapeutic goods referred to the Office of Medicines Authorisation of the Therapeutic Goods Administration within the Department for the purpose of evaluation as a non-prescription medicine

**[61] Schedules 12 and 13***omit*

(within the meaning of section 9D of the Act)

**[62] Schedule 14, heading***substitute***Schedule 14 Designated active ingredients**

(regulation 2)

**[63] Further amendments**

<i>Provision</i>	<i>omit each mention of</i>	<i>insert</i>
Paragraph 43AAJ (1) (b)	\$78 600	\$81 300
Paragraph 45 (4A) (a)	\$8 770	\$9 070
Paragraph 45 (4A) (b)	\$7 300	\$7 550
Paragraph 45 (4A) (d)	\$29 400	\$30 400
Subregulation 45 (9)	\$4 390	\$4 540

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<i>Provision</i>	<i>omit each mention of</i>	<i>insert</i>
Subregulation 45 (11)	\$1 610	\$1 660
Schedule 9, Part 2, item 1A	380	390
Schedule 9, Part 2, item 1	1 390	1 440
Schedule 9, Part 2, item 1	17 300	17 900
Schedule 9, Part 2, item 1	14 600	15 100
Schedule 9, Part 2, item 1	2 200	2 270
Schedule 9, Part 2, item 2	1 260	1 300
Schedule 9, Part 2, item 2	1 170	1 210
Schedule 9, Part 2, item 2	3 500	3 620
Schedule 9, Part 2, item 2	1 750	1 810
Schedule 9, Part 2, item 2	10 200	10 500
Schedule 9, Part 2, item 2	550	570
Schedule 9, Part 2, item 2	590	610
Schedule 9, Part 2, item 2AA	530	550
Schedule 9, Part 2, item 2A	1 350	1 400
Schedule 9, Part 2, item 2A	1 260	1 300
Schedule 9, Part 2, item 2A	330	340
Schedule 9, Part 2, item 2A	360	370
Schedule 9, Part 2, item 2AB	340	350
Schedule 9, Part 2, items 2B and 2C	4 390	4 540
Schedule 9, Part 2, item 3	360	370
Schedule 9, Part 2, item 3	660	680
Schedule 9, Part 2, item 3AA	530	550
Schedule 9, Part 2, item 5	8 390	8 680
Schedule 9, Part 2, item 5	10 800	11 200
Schedule 9, Part 2, item 5	14 700	15 200
Schedule 9, Part 2, item 5	19 600	20 300
Schedule 9, Part 2, item 5	29 400	30 400

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<i>Provision</i>	<i>omit each mention of</i>	<i>insert</i>
Schedule 9, Part 2, item 5	39 200	40 500
Schedule 9, Part 2, item 5	58 700	60 700
Schedule 9, Part 2, item 5	3 030	3 130
Schedule 9, Part 2, item 5A	4 390	4 540
Schedule 9, Part 2, item 5B	14 600	15 100
Schedule 9, Part 2, item 6	25 700	26 600
Schedule 9, Part 2, item 6	17 500	18 100
Schedule 9, Part 2, item 6	29 400	30 400
Schedule 9, Part 2, item 6AA	310	320
Schedule 9, Part 2, item 6AB	550	570
Schedule 9, Part 2, item 6ABA	1 660	1 720
Schedule 9, Part 2, item 6AC	940	970
Schedule 9, Part 2, item 6AD	17 500	18 100
Schedule 9, Part 2, item 6AD	4 390	4 540
Schedule 9, Part 2, item 6A	1 170	1 210
Schedule 9, Part 2, item 6B	2 940	3 040
Schedule 9, Part 2, item 6C	6 390	6 610
Schedule 9, Part 2, item 6D	8 390	8 680
Schedule 9, Part 2, item 6D	10 800	11 200
Schedule 9, Part 2, item 6D	14 700	15 200
Schedule 9, Part 2, item 6D	19 600	20 300
Schedule 9, Part 2, item 6D	29 400	30 400
Schedule 9, Part 2, item 6D	39 200	40 500
Schedule 9, Part 2, item 6D	58 700	60 700
Schedule 9, Part 2, item 7	8 770	9 070
Schedule 9, Part 2, item 7	7 300	7 550
Schedule 9, Part 2, item 7	29 400	30 400
Schedule 9, Part 2, item 7A	8 390	8 680
Schedule 9, Part 2, item 7A	10 800	11 200

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<i>Provision</i>	<i>omit each mention of</i>	<i>insert</i>
Schedule 9, Part 2, item 7A	14 700	15 200
Schedule 9, Part 2, item 7A	19 600	20 300
Schedule 9, Part 2, item 7A	29 400	30 400
Schedule 9, Part 2, item 7A	39 200	40 500
Schedule 9, Part 2, item 7A	58 700	60 700
Schedule 9, Part 2, item 7B	8 390	8 680
Schedule 9, Part 2, item 7B	10 800	11 200
Schedule 9, Part 2, item 7B	14 700	15 200
Schedule 9, Part 2, item 7B	19 600	20 300
Schedule 9, Part 2, item 7B	29 400	30 400
Schedule 9, Part 2, item 7B	39 200	40 500
Schedule 9, Part 2, item 7B	58 700	60 700
Schedule 9, Part 2, item 8	810	840
Schedule 9, Part 2, item 9	530	550
Schedule 9, Part 2, item 9	1 090	1 130
Schedule 9, Part 2, item 9AA	530	550
Schedule 9, Part 2, item 9AB	730	750
Schedule 9, Part 2, items 9AC and 9ACA	530	550
Schedule 9, Part 2, item 9AD	1 050	1 090
Schedule 9, Part 2, item 9AD	9 080	9 390
Schedule 9, Part 2, item 9AD	20 200	20 900
Schedule 9, Part 2, item 9AD	27 100	28 000
Schedule 9, Part 2, item 9AD	42 400	43 800
Schedule 9, Part 2, item 9AD	56 300	58 200
Schedule 9, Part 2, item 9AD	68 600	70 900
Schedule 9, Part 2, items 9B and 9C	14 600	15 100
Schedule 9, Part 2, items 14 and 14A	280	290

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<i>Provision</i>	<i>omit each mention of</i>	<i>insert</i>
Schedule 9, Part 2, item 17	190	200
Schedule 9, Part 2, item 17	240	250
Schedule 9, Part 2, item 17	380	390
Schedule 9, Part 2, item 17A	960	990
Schedule 9, Part 2, item 17A	500	520
Schedule 9, Part 2, item 17A	730	750
Schedule 9, part 2, item 17A	200	210
Schedule 9, Part 2, item 17A	350	360
Schedule 9, Part 2, item 17A	250	260
Schedule 9, Part 2, item 17A	190	200
Schedule 9, Part 2, item 17A	240	250
Schedule 9, Part 2, item 17A	380	390
Schedule 9, Part 2, item 18	1 770	1 830

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### 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>.