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Statutory Rules 1996 No. <sup>L1</sup> 131/

## Therapeutic Goods Regulations<sup>2</sup> (Amendment)

I, THE 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 <sup>L</sup> 1996. 28 June/

<sup>L</sup> WILLIAM DEANE/  
Governor-General

By His Excellency's Command,

<sup>L</sup>  
Parliamentary Secretary  
to the Minister for Health and Family Services  
for the Minister for Health and Family Services

R. L. WOODS/

### 1. Commencement

1.1 These Regulations commence on 1 July 1996.

**2. Amendment**

2.1 The Therapeutic Goods Regulations are amended as set out in these Regulations.

**3. Regulation 45 (Waiver or reduction of fees)**

3.1 Paragraph 45 (4A) (a):

Omit "\$2,700"; substitute "\$2,860".

3.2 Paragraph 45 (4A) (b):

Omit "\$1,600", substitute "\$1,665".

3.3 Paragraph 45 (4A) (c):

Omit "\$2,400", substitute "\$2,495".

3.4 Paragraph 45 (4A) (d):

Omit "\$9,500", substitute "\$10,000".

3.5 Paragraph 45 (4A) (e):

Omit "\$3,200", substitute "\$3,360".

3.6 Paragraph 45 (9) (a):

Omit "\$2,700", substitute "\$2,860".

3.7 Paragraph 45 (9) (b):

Omit "\$1,600", substitute "\$1,665".

3.8 Paragraph 45 (9) (c):

Omit "\$2,400", substitute "\$2,495".

3.9 Paragraph 45 (9) (d):

Omit "\$3,200", substitute "\$3,360".

3.10 Paragraph 45 (11) (a):

Omit "\$900", substitute "\$955".

3.11 Paragraph 45 (11) (b):

Omit "\$550", substitute "\$570".

3.12 Paragraph 45 (11) (c):

Omit "\$800", substitute "\$830".

3.13 Paragraph 45 (11) (d):  
Omit "\$3,200", substitute "\$3,360".

#### 4. Schedule 9 (Fees)

##### 4.1 Item 2:

Omit "if regulation 43A does not apply", substitute "if regulation 43A does not apply and the application is not an application to which item 2AA applies".

##### 4.2 After item 2, insert:

"2AA Application fee for the purposes of 380".  
paragraph 23 (2) (a) of the Act for the  
registration of therapeutic goods if the  
previous registration was cancelled solely  
because of failure to pay the annual  
registration charge and the application is  
made within 30 days of the cancellation

##### 4.3 Item 3:

Omit "if regulation 43A does not apply", substitute "if regulation 43A does not apply and the application is not an application to which item 3AA applies".

##### 4.4 After item 3, insert:

"3AA Application fee for the purposes of 200".  
paragraph 23 (2) (a) of the Act for the listing  
of therapeutic goods if the previous listing  
was cancelled solely because of failure to  
pay the annual listing charge and the  
application is made within 30 days of the  
cancellation

## 4.5 After item 6, insert:

- “6AA fee for evaluation of data to determine whether the manufacturing and quality control procedures used in the manufacture of goods, a step in the manufacture of which was carried out outside Australia, are acceptable for the purposes of paragraph 25 (1) (g), 26 (1) (g), or 31 (1) (e) of the Act (in addition to any other fee payable under this Schedule in relation to an evaluation or assessment of an application to include therapeutic goods in the Register) 120
- “6AB fee for evaluation of data for the purposes of subsection 32 (3), (4) or (5) of the Act in relation to goods if a step in the manufacture of the goods has been carried out outside Australia 120”.

## 4.6 Item 9:

Omit the item, substitute:

- “9 inspection fee for the purposes of paragraphs 38 (1) (c), 41 (1) (f) and 58 (3) (b) of the Act is as follows:
- (a) in relation to the manufacture of a single sterile or non-sterile type of therapeutic device:
    - (i) initial period of inspection (up to 4 hours):
      - (A) for inspection within Australia; 1,400
      - or
      - (B) for inspection outside Australia; 1,800
      - and

- (ii) each additional period of 2 hours, or in part of 2 hours:
    - (A) for inspection within Australia; or 450
    - (B) for inspection outside Australia; 600
- (b) in relation to the manufacture of a single sterile or non-sterile drug:
  - (i) initial period of inspection (up to 4 hours):
    - (A) for inspection within Australia; or 1,400
    - (B) for inspection outside Australia; and 1,800
  - (ii) each additional period of 2 hours, or a part of 2 hours:
    - (A) for inspection within Australia; or 450
    - (B) for inspection outside Australia; 600
- (c) in relation to the manufacture of therapeutic goods, to which paragraph (a) or (b) does not apply, that are or are represented to be sterile:
  - (i) initial period of inspection (up to 4 hours):
    - (A) for inspection within Australia; or 2,700

	(B) for inspection outside Australia; and	3,400
(ii)	each additional period of 2 hours, or a part of 2 hours:	
	(A) for inspection within Australia; or	800
	(B) for inspection outside Australia;	1,100
(d)	in relation to the manufacture of therapeutic goods to which paragraph (a) or (b) does not apply that are not sterile:	
	(i) initial period of inspection (up to 4 hours):	
	(A) for inspection within Australia; or	2,700
	(B) for inspection outside Australia; and	3,400
	(ii) each additional period of 2 hours, or a part of 2 hours:	
	(A) for inspection within Australia; or	800
	(B) for inspection outside Australia;	1,100
(e)	in relation to a single step in the manufacture of therapeutic goods:	
	(i) initial period of inspection (up to 4 hours):	
	(A) for inspection within Australia; or	1,400

- |  |       |
|--|-------|
| (B) for inspection outside Australia; and  | 1,800 |
| (ii) each additional period of 2 hours, or a part of 2 hours:  |       |
| (A) for inspection within Australia; or  | 450   |
| (B) for inspection outside Australia;  | 600   |
| (f) in relation to the manufacture of ingredients or components for use in the manufacture of therapeutic goods, and paragraph (e) does not apply: |       |
| (i) initial period of inspection (up to 4 hours):  |       |
| (A) for inspection within Australia; or  | 1,400 |
| (B) for inspection outside Australia; and  | 1,800 |
| (ii) each additional period of 2 hours, or a part of 2 hours:  |       |
| (A) for inspection within Australia; or  | 450   |
| (B) for inspection outside Australia;  | 600   |
| (g) in relation to the manufacture of herbal or homoeopathic preparations that are not included in a Schedule of the Poisons Standard:             |       |
| (i) initial period of inspection (up to 4 hours):  |       |

(A) for inspection within Australia;		1,400
or		
(B) for inspection outside Australia;		1,800
and		
(ii) each additional period of 2 hours, or a part of 2 hours:		
(A) for inspection within Australia;		450
or		
(B) for inspection outside Australia;		600
(h) in relation to the manufacture of herbal or homoeopathic preparations that are included in Schedule 5 or 6 of the Poisons Standard:		
(i) initial period of inspection (up to 4 hours):		
(A) for inspection within Australia;		1,400
or		
(B) for inspection outside Australia;		1,800
and		
(ii) each additional period of 2 hours, or a part of 2 hours:		
(A) for inspection within Australia;		450
or		
(B) for inspection outside Australia;		600
(j) in relation to the manufacture of diagnostic goods for in vitro use:		
(i) initial period of inspection (up to 4 hours):		



(A) for inspection within Australia; or	1,400
(B) for inspection outside Australia; and	1,800
(ii) each additional period of 2 hours, or a part of 2 hours:	
(A) for inspection within Australia; or	450
(B) for inspection outside Australia	600".

4.7 Schedule 9 is amended as set out in the following table:

Column 1 Item, paragraph or subparagraph	Column 2 Omit	Column 3 Substitute
2 (a)	360	380
2 (b)	460	500
2 (c)	1,200	1,300
2 (d)	600	630
2 (e)	230	250
2 (f)	180	200
2 (g)	360	380
2A (a)	360	380
2A (b)	150	200
2A (c)	150	200
3	150	200
4 (a) (i)	3,600	3,800
4 (a) (ii)	11,400	12,000
4 (a) (iii)	25,600	27,000
4 (a) (iv)	49,700	52,500
4 (a) (v)	61,400	65,000
4 (b) (i)	7,100	7,500

Column 1 Item, paragraph or subparagraph	Column 2 Omit	Column 3 Substitute
4 (b) (ii)	25,600	27,000
4 (b) (iii)	39,800	42,000
4 (c) (i)	460	500
4 (c) (ii)	4,200	4,400
4 (c) (iii)	9,100	9,600
4 (c) (iv)	12,500	13,120
4 (c) (v)	20,100	21,100
4 (c) (vi)	27,800	29,200
5 (a)	2,100	2,200
5 (b)	460	500
5A	2,100	2,200
6 (a)	8,300	8,800
6 (b)	4,800	5,000
6 (c)	4,800	5,000
6 (d)	9,500	10,000
6A	460	500
7 (a)	2,700	2,900
7 (b)	1,600	1,700
7 (c)	2,400	2,500
7 (d)	9,500	10,000
7 (e)	3,200	3,360
8	360	380
9A	3,200	4,000
14 (a)	150	175
14A	150	175

### NOTES

1. Notified in the *Commonwealth of Australia Gazette* on 28 June 1996.
2. 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 and 25.