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F.R.L.I.

1996B00415

Statutory Rules 1993 No. *h<sup>1</sup>*

*141* |

## 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 *22 June* 1993.

**BILL HAYDEN**  
Governor-General

By His Excellency's Command,

*ROSEMARY CROWLEY*  
Minister for Family Services

### 1. Commencement

1.1 These Regulations commence on 1 July 1993.

### 2. Amendment

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

**3. Schedule 9 (Fees)**

## 3.1 Item 2:

Omit “23 (c)”, substitute “23 (2) (a)”.

## 3.2 Item 2, paragraph (a):

Omit “300”, substitute “320”.

## 3.3 Item 2, paragraph (b):

Omit “nil”, substitute “390”.

## 3.4 Item 2, paragraph (c):

Omit “1,000”, substitute “1,100”.

## 3.5 Item 2, paragraph (d), column 2:

Omit all the words before subparagraph (i), substitute “subject to paragraphs (e) and (f), if a person submits more than one application at the same time and:”.

## 3.6 Item 2, paragraph (d), column 3:

Omit “500”, substitute “530”.

## 3.7 Item 2:

Add at the end:

- “(e) if a person submits at the same time more than one application relating to item 4 (c) (i) and (ii): 200
- (i) each of which relates to goods that contain the same therapeutically active ingredient; and
  - (ii) the information in support of each of which is sufficiently common in respect of the goods to enable a simultaneous evaluation of the goods to be made;
- for each additional application of less than 50 pages

- (f) if a person submits at the same time more than one application relating to item 5 and: 160”.
- (i) each of which relates to goods that contain the same therapeutically active ingredient; and
  - (ii) the information in support of each of which is sufficiently common in respect of the goods to enable a simultaneous evaluation of the goods to be made;
- for each additional application

3.8 After item 2, insert:

- “2 A fee for processing (not including evaluation) of data for the purposes of 32 (3), (4) or (5) of the Act in relation to the variation of an entry in the Register in respect of therapeutic goods :
- “(a) if the variation is in respect of: 320
    - (i) a drug to which item 4 or 5 applies; or
    - (ii) a therapeutic device to which Part 1 of Schedule 3 applies
  - (b) if the variation is in respect of a therapeutic device to which Part 2 of Schedule 3 applies 90
  - (c) if the variation is in respect of the listing of therapeutic goods 90”.

3.9 Item 3, column 2:

Omit “23 (c)”, substitute “23 (2) (a)”.

3.10 Item 3, column 3:

Omit “60”, substitute “90”.

3.11 Item 4, subparagraph (a) (i):

Omit “3,000”, substitute “3,200”.

3.12 Item 4, subparagraph (a) (ii):

Omit “9,600”, substitute “10,200”.

## 3.13 Item 4, subparagraph (a) (iii):

Omit "21,600", substitute "22,900".

## 3.14 Item 4, subparagraph (a) (iv):

Omit the subparagraph, substitute:

- |                                                           |          |
|-----------------------------------------------------------|----------|
| “(iv) more than 2,000 pages but not more than 5,000 pages | 44,500   |
| (v) more than 5,000 pages                                 | 54,600”. |

## 3.15 Item 4, subparagraph (b) (i):

Omit "6,000", substitute "6,400".

## 3.16 Item 4, subparagraph (b) (ii):

Omit the subparagraph, substitute:

- |                                                         |          |
|---------------------------------------------------------|----------|
| “(ii) more than 200 pages but not more than 2,000 pages | 22,900   |
| (iii) more than 2,000 pages                             | 35,300”. |

## 3.17 Item 4, subparagraph (c) (i):

Omit "350", substitute "390".

## 3.18 Item 4, subparagraph (c) (ii):

Omit "3,480", substitute "3,700".

## 3.19 Item 4, subparagraph (c) (iii):

Omit the subparagraph, substitute:

- |                                                       |          |
|-------------------------------------------------------|----------|
| “(iii) more than 50 pages but not more than 100 pages | 8,200    |
| (iv) more than 100 pages                              | 10,600”. |

## 3.20 Item 5:

Omit the item, substitute:

- |     |                                                                                                                                                                                                                              |       |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| “5  | fee for evaluation:                                                                                                                                                                                                          |       |
| (a) | for the purposes of subsection 24 (1) of the Act in respect of a drug to which item 4 does not apply;                                                                                                                        | 1,800 |
| (b) | of data for the purposes of subsection 32 (3), (4) or (5) of the Act in relation to an entry in the Register relating to a drug, other than a drug entered in the Register because of payment of a fee specified in item 4”. | 390”. |

3.21 Item 5A:

Omit "1,700", substitute "1,800".

3.22 Item 6:

After "therapeutic device", insert "to which Part 1 of Schedule 3 applies".

3.23 Item 6, paragraph (a):

Omit "7,000", substitute "7,500".

3.24 Item 6, paragraphs (b) and (c):

Omit "4,000", substitute "4,300".

3.25 Item 6, paragraph (d):

Omit "8,000", substitute "8,500".

3.26 After item 6, insert:

"6 A fee for evaluation of data for the purposes of subsection 390".  
32 (3), (4) or (5) of the Act in relation to an entry in the  
Register relating to a therapeutic device to which Part 2  
of Schedule 3 applies

3.27 Item 7:

Omit "registered device", substitute "therapeutic device to which Part 1 of Schedule 3 applies".

3.28 Item 7, paragraph (a):

Omit "2,300", substitute "2,500".

3.29 Item 7, paragraph (b):

Omit "1,300", substitute "1,400".

3.30 Item 7, paragraph (c):

Omit "2,000", substitute "2,200".

3.31 Item 7, paragraph (d):

Omit "8,000", substitute "8,500".

3.32 Item 8:

Omit "300", substitute "320".

3.33 Item 9, subparagraph (a) (i):

Omit "2,400", substitute "2,600".

- 3.34 Item 9, subparagraph (a) (ii):  
Omit “1,400”, substitute “1,500”.
- 3.35 Item 9, subparagraph (b) (i):  
Omit “2,400”, substitute “2,600”.
- 3.36 Item 9, subparagraph (b) (ii):  
Omit “1,400”, substitute “1,500”.
- 3.37 Item 9, subparagraph (c) (i):  
Omit “2,400”, substitute “2,600”.
- 3.38 Item 9, subparagraph (c) (ii):  
Omit “1,400”, substitute “1,500”.
- 3.39 Item 9, subparagraph (d) (i):  
Omit “1,200”, substitute “1,300”.
- 3.40 Item 9, subparagraph (d) (ii):  
Omit “800”, substitute “850”.
- 3.41 Item 9, subparagraph (e) (i):  
Omit “1,200”, substitute “1,300”.
- 3.42 Item 9, subparagraph (e) (ii):  
Omit “800”, substitute “850”.
- 3.43 Item 9, subparagraph (f) (i):  
Omit “1,200”, substitute “1,300”.
- 3.44 Item 9, subparagraph (f) (ii):  
Omit “800”, substitute “850”.
- 3.45 After item 9, insert:
- “9 A fee in respect of the evaluation of steps in the manufacture of therapeutic goods under paragraph 25 (1) (g) or (h), 26 (1) (g) or (h), 38 (1) (c), 41 (1) (f) or 58 (3) (b) of the Act by reference to data relating to premises where manufacture of the goods takes place, being data contained in a file that is commonly called the plant master file 2,000”.

## 3.46 Item 12:

Omit all the words in column 2, substitute:

“fee for evaluation of data in relation to therapeutic goods specified in Schedule 10 for the purposes of subsection 32 (3), (4) or (5) of the Act”

## 3.47 Item 14:

Omit “60”, substitute “90”.

## 3.48 Item 15 (first occurring):

Omit “350”, substitute “390”.

## 3.49 Item 15 (second occurring), column 1:

Omit “15”, substitute “16”.

## NOTES

1. Notified in the *Commonwealth of Australia Gazette* on *L* 1993.
2. Statutory Rules ~~1990 No. 88~~ amended by 1990 No. 394; 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332 and 370.

*25 June*  
*as amended by 2/*  
*and 430/*