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Therapeutic Goods Amendment Regulations 2000 (No. 6)¹

Statutory Rules 2000 No. ²

267

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 **27 SEP 2000** 2000

WILLIAM DEANE

Governor-General

By His Excellency's Command

GRANT TAMBLING

Parliamentary Secretary to the Minister for Health
and Aged Care

Regulation 1

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2000* (No. ~~1~~).

6

2 Commencement

These Regulations commence on gazettal.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments

(regulation 3)

[1] After regulation 43AA

insert

43AB Circumstances in which inspection fee covered by annual charge

- (1) A fee is not payable in accordance with item 9AB of Schedule 9 for an inspection covered by the annual charge for a licence to manufacture the therapeutic goods mentioned in that item.
- (2) An inspection is covered by the annual charge for a licence to manufacture the therapeutic goods if no more than 2 prior inspections have been carried out at the metropolitan site, identified in the licence, within the period of 3 years immediately preceding the relevant inspection.
- (3) In this regulation:
inspection means an inspection in relation to a metropolitan site.

2

Therapeutic Goods Amendment Regulations 2000 (No. ~~1~~)

2000, ~~1~~

6 267

[2] Paragraph 45 (4A) (c)

omit

reduced by

insert

reduced to

[3] Regulation 45A

omit

If the wholesale turnover

insert

(1) Subject to subregulation (2), if the wholesale turnover

[4] Regulation 45A

insert

(2) Subregulation (1) does not apply in relation to the annual charge payable in respect of a licence that is in force for the manufacture of human blood and blood components.

[5] Schedule 9, item 9, paragraph (a)

omit

within Australia

insert

within Australia (except for therapeutic goods mentioned in items 9AB and 9AC)

[6] Schedule 9, item 9A*substitute*

9A	fee for paragraph 25 (1) (g) or (h), or 26 (1) (g) or (h) of the Act (and, in relation to associated inspections, for paragraphs 38 (1) (c), 41 (1) (f) and 58 (3) (b) of the Act), in respect of the evaluation of steps in the manufacture of therapeutic goods (except in relation to goods mentioned in item 9AD), by reference to data in relation to premises where manufacture of the goods takes place, being data contained in a file known as the plant master file	5 625
9AB	fee for inspection (including an inspection for paragraph 58 (3) (b) of the Act) of manufacturing premises or operations for the preparation of human blood and blood components under licence, at the metropolitan site covered by the licence, for each inspector engaged per hour, or part of an hour	500
9AC	fee for inspection (including an inspection for paragraph 58 (3) (b) of the Act) of manufacturing premises or operations for the preparation of human blood and and blood components under licence, at a site covered by the licence other than the metropolitan site, for each inspector engaged per hour, or part of an hour	355
9AD	fee for paragraph 25 (1) (g) or (h), or 26 (1) (g) or (h) of the Act (and, in relation to associated inspections, for paragraphs 38 (1) (c), 41 (1) (f) and 58 (3) (b) of the Act), in respect of the evaluation of the manufacture of human blood and blood components prepared under licence by reference to data contained in files known as technical master files or plasma master files, where the total number of pages of each file referred to is:	
	(a) not over 10 pages	725
	(b) over 10 pages, but not over 50 pages	6 200
	(c) over 50 pages, but not over 100 pages	13 750
	(d) over 100 pages, but not over 1 000 pages	18 500

(e) over 1 000 pages, but not over 3 000 pages	29 000
(f) over 3 000 pages, but not over 4 000 pages	38 500
(g) over 4 000 pages	47 000

Notes

- 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 and 124.

- Notified in the *Commonwealth of Australia Gazette* on / 2000.

28 September