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Therapeutic Goods (Charges) Amendment Regulations 2002 (No. 2)¹

Statutory Rules 2002 No. ²

235

I, PETER JOHN HOLLINGWORTH, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods (Charges) Act 1989*.

Dated - 3 OCT 2002 2002

PETER HOLLINGWORTH

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 (Charges) Amendment Regulations 2002 (No. 1)*.

2

2 Commencement

These Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002*.

3 Amendment of *Therapeutic Goods (Charges) Regulations 1990*

Schedule 1 amends the *Therapeutic Goods (Charges) Regulations 1990*.

Schedule 1 Amendments

(regulation 3)

[1] Regulation 2

omit

In these Regulations,

insert

- (1) In these Regulations,

[2] Regulation 2

insert

- (2) In these Regulations, a reference to a medical device of a particular class is a reference to a medical device classified as that class under Division 3.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

[3] After subregulation 3 (1A)*insert*

- (1B) For the purposes of subsection 4 (1B) of the Act, the annual charges in respect of the inclusion of kinds of medical devices in the Register under Chapter 4 of the *Therapeutic Goods Act 1989* that has effect at any time during a financial year are as follows:
- (a) for a Class I medical device (other than a Class I medical device to which paragraph (b) applies) — \$40;
 - (b) for a Class IIb medical device, Class IIa medical device, or Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function — \$620;
 - (c) for a Class AIMD medical device or Class III medical device — \$820.

[4] Subregulation 3 (3), note*omit*

Part 4

insert

Part 3-3

[5] Subregulation 4B (1)*substitute*

- (1) For the purposes of subsection 5 (3) of the Act, annual charges in respect of the registration or listing of therapeutic goods, or the inclusion of kinds of medical devices in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*, are not payable by persons whose turnover of those goods or devices is declared under regulation 4C to be of low volume and low value.

[6] Subregulation 4C (1)

omit

therapeutic goods

insert

therapeutic goods, or kinds of medical devices that are included in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*,

[7] Paragraph 4C (2) (b)

omit

for

insert

under

[8] Subregulation 4C (5)

omit

listing

insert

listing, or inclusion in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*,

[9] After subregulation 4C (5)

insert

- (6) If the applicant has not received notice of the Secretary's decision in relation to the application within 40 days after making the application, the Secretary is taken to have refused the application under paragraph (3) (b).

[10] Subregulation 4E (1)*omit*

For paragraph 63 (2) (h) of the *Therapeutic Goods Act 1989*, as incorporated, and read as one, with the Act,

insert

For paragraph 4C (2) (b),

[11] Regulation 4F*omit*

paragraph 4C (3) (b)

insert

paragraph 4C (3) (b), or an assumed decision under subregulation 4C (6),

[12] Subregulation 5 (2)*omit*

subregulation 3 (1)

insert

subregulation 3 (1), (1A) or (1B)

Notes

1. These Regulations amend Statutory Rules 1990 No. 395, as amended by 1991 No. 85; 1992 No. 88; 1993 No. 140; 1994 Nos. 149 and 223; 1995 No. 193; 1996 No. 132; 1997 No. 161; 1998 Nos. 246 and 260; 2000 Nos. 71, 125 and 266; 2001 No. 161; 2002 No. 144.

2. Notified in the *Commonwealth of Australia Gazette* on 2 2002.

4 October