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Office of Legislative Drafting, Attorney-General's
Department.



Statutory Rules 1998 No. ¹/_h

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Therapeutic Goods (Charges) Amendment Regulations 1998 (No. ²/_h)²

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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 (Charges) Act 1989*.

Dated 11 AUG 1998 1998.

WILLIAM DEANE
Governor-General

By His Excellency's Command,

TRISH WORTH
Parliamentary Secretary
to the Minister for Health and Family Services
for the Minister for Health and Family Services

1. Name of regulations

1.1 These regulations are the *Therapeutic Goods (Charges) Amendment Regulations 1998 (No. ²/_h)*.

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2. Commencement

2.1 These regulations commence on gazettal.

3. Amendment

3.1 The Therapeutic Goods (Charges) Regulations are amended as set out in these regulations.

4. Regulation 1 (Citation)

4.1 Omit the regulation, substitute:

Name of regulations

“1. These regulations are the *Therapeutic Goods (Charges) Regulations 1990*.”.

5. Regulation 4 (Charges not payable when turnover is of low volume and low value)

5.1 Omit the regulation.

6. New regulations 4B, 4C, 4D, 4E and 4F

6.1 After regulation 4A, insert:

Charges not payable when turnover is of low volume and low value

“4B. (1) For subsection 5 (3) of the Act, annual charges in respect of the registration or listing of therapeutic goods are not payable by persons whose turnover of those goods is of low volume and low value.

“(2) Regulation 4C explains how to work out whether turnover is of low volume and low value.

Turnover of low volume and low value

“4C. (1) A person who has turnover, or expects to have turnover, of particular registered or listed therapeutic goods may apply to the Secretary for a declaration that the turnover is of low volume and low value.

“(2) The application must:

- (a) be made using an application form approved in writing by the Secretary; and
- (b) be accompanied by the application fee for regulation 4E.

“(3) On receiving an application, the Secretary must, as soon as practicable:

- (a) make the declaration; or
- (b) refuse the application.

“(4) In considering the application, the Secretary may take into account:

- (a) the value of the wholesale turnover of the goods in the financial year immediately before the financial year to which the charge relates; or
- (b) if there was no turnover of those goods in the preceding financial year — the value of the estimated wholesale turnover of the goods in the financial year immediately after the financial year to which the charge relates.

“(5) However, the Secretary must make a declaration if the Secretary is satisfied that the charge for registration or listing that would be payable, if the application was refused, is more than:

- (a) 6% of the value of the wholesale turnover of those goods in the financial year immediately before the financial year to which the charge relates; or
- (b) if there was no turnover of those goods in that preceding financial year — 6% of the value of the estimated wholesale turnover of those goods in the financial year immediately after the financial year to which the charge relates.

Delegation

“4D. (1) The Secretary may delegate, in writing, to an officer of the Department, the Secretary’s power under regulation 4C to make a declaration or refuse an application.

“(2) A person exercising a power under a delegation under this regulation must comply with any conditions imposed or directions given by the Secretary.

Application fee

“4E. (1) For paragraph 63 (2) (h) of the *Therapeutic Goods Act 1989*, as incorporated, and read as one, with the Act, the fee for making an application is \$70.

“(2) However, if the total amount of application fees incurred by the applicant in a year reaches \$10,000, the applicant is not required to pay all or part of an application fee for any more applications made in the year.

Review of decisions

“4F. Application may be made to the Administrative Appeals Tribunal for review of a decision by the Secretary under paragraph 4C (3) (b) to refuse an application.”.

7. Regulation 5 (Charges payable where estimate of turnover is too low)

7.1 Paragraph 5 (1) (a):

Omit “estimated under paragraph 4 (2) (b); and”, substitute “taken into account for paragraph 4C (4) (b) or paragraph 4C (5) (b); and”.

NOTES

1. Notified in the *Commonwealth of Australia Gazette* on / 1998.
2. 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 No. 246.

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