

(Statutory Rules and Territory Ordinances)
Administering Department: please include this copy in documents sent to Federal Executive Council Secretariat in connection with making of this legislation. Ex. Co. Secretariat: please complete this copy by insertion of signatures and date of making, and send to Legislative Services Section, Commercial & Drafting Division, Attorney-General's Department.



Statutory Rules 1990 No. ¹

395/

Therapeutic Goods (Charges) Regulations

I, THE GOVERNOR-GENERAL of the Commonwealth of Australia, acting with the advice of the Federal Executive Council and under section 4 of the *Acts Interpretation Act 1901*, hereby make the following Regulations under the *Therapeutic Goods (Charges) Act 1989*.

Dated 29 November 1990.

BILL HAYDEN

Governor-General

By His Excellency's Command,

Michael Tate.
State for
Minister of Justice and Consumer Affairs
for and on behalf of the.
Minister of State for Community Services
and Health

Citation

1. These Regulations may be cited as the Therapeutic Goods (Charges) Regulations.

Interpretation

2. In these Regulations, unless the contrary intention appears:

“**Poisons Standard**” means the current edition of the *Standard for the uniform scheduling of drugs and poisons* published by the National Health and Medical Research Council;

“**the Act**” means the *Therapeutic Goods (Charges) Act 1989*.

Charges

3. (1) For the purposes of subsection 4 (1) of the Act, the annual charges for the registration or listing of therapeutic goods are:

(a) for therapeutic goods whose registration is in force at any time during a financial year:

(i) if the goods are drugs that are included in Schedule 4 or 8 to the Poisons Standard—\$350; or

(ii) in any other case—\$175;

- (b) for therapeutic goods (other than therapeutic goods produced for export) whose listing is in force at any time during a financial year—\$60.

(2) For the purpose of subsection 4 (2) of the Act, the annual charge for a licence that is in force at any time during a financial year is:

- (a) if the licence is for:
 - (i) the manufacture of therapeutic goods; or
 - (ii) the manufacture of containers in which therapeutic goods are to be packed;
 \$3,000; or
- (b) if the licence is for:
 - (i) the manufacture of ingredients or components for use in the manufacture of therapeutic goods; or
 - (ii) a single step in the manufacture of therapeutic goods; or
 - (iii) the manufacture of a single drug or device that is, or is represented to be, sterile;
 \$1,500; or
- (c) if the licence is for the manufacture of herbal or homoeopathic preparations that are not included in a Schedule to the Poisons Standard—\$1,000.

(3) If, but for this subregulation, more than one charge referred to in subregulation (1) or (2) would otherwise apply in respect of a financial year in relation to:

- (a) the registration or listing of particular goods; or
- (b) a particular licence;

the charge that is the greatest applicable charge is the only charge that applies in respect of the registration or listing of those goods or in relation to that licence in that year.

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

4. (1) In spite of regulation 3, annual charges for the registration or listing of therapeutic goods are not payable by persons whose wholesale turnover of those therapeutic goods is of low volume and low value.

(2) For the purposes of subregulation (1), the wholesale turnover of therapeutic goods is of low volume and low value if the charge that would, but for this regulation, be payable for the registration or listing of those goods in a financial year is greater than:

- (a) 2% of the value of the wholesale turnover of those goods in the financial year immediately before the financial year to which the fee relates; or
- (b) if there was no turnover of those goods in that preceding financial year—2% of the value of the estimated wholesale turnover of those goods in the financial year immediately after the financial year to which the fee relates.

Charges payable where estimate of turnover is too low

5. (1) If:

- (a) the value of the wholesale turnover of therapeutic goods for a financial year is estimated under paragraph 4 (2) (b); and
- (b) the actual wholesale turnover of those goods in that financial year is so high that those goods would not have been regarded as being of low volume and low value;

the wholesale turnover of those goods for that financial year is not to be regarded as being of low volume and low value.

(2) If the wholesale turnover of therapeutic goods is not to be regarded as being of low volume and low value, the charge payable under regulation 3 is payable immediately.

NOTE

1. Notified in the *Commonwealth of Australia Gazette* on

L

1990.

6 December)