

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

1998 No. 260

EXPLANATORY STATEMENT

STATUTORY RULES 1998 NO. 260

Issued by authority of the Minister for Health and Family Services

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 1998

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or are exported from Australia. Under that Act therapeutic goods, unless they have been exempted from this requirement, are required to be registered or listed in the Australian Register of Therapeutic Goods (the Register) before they may be manufactured, supplied, imported or exported.

Section 3 of the *Therapeutic Goods (Charges) Act 1989* (the Charges Act) states that the *Therapeutic Goods Act 1989* is incorporated, and is to be read as one, with the Charges Act.

Subsection 4(1) of the Charges Act provides that annual charges are payable for maintaining registrations and listings of therapeutic goods in the Register. Section 5 of the Charges Act enables the Governor-General to prescribe the level of the charges that are payable. Subsection 5(3) of the Charges Act states the regulations must provide that annual charges will not be payable for registrations or listings of goods where their annual turnover is of low volume and low value. Turnover would be of low volume and low value where, for example, the annual charge payable for maintaining a registration or listing of therapeutic goods will be greater than 6% of the value of the wholesale turnover of those goods in the previous financial year to that for which the charge relates.

The purpose of the regulations is to insert provisions to enable an application to be lodged for a declaration by the Secretary that a registration or listing for particular therapeutic goods registered or listed in the name of the applicant has an annual turnover that is of low volume and low value. Where the Secretary makes such a declaration in relation to a particular registration or listing, the applicant will not be required to pay an annual registration or listing charge. This provision has the agreement of industry. To give effect to this proposal, the regulations:

- (a) insert a new provision describing how an application for a declaration may be made by an applicant (regulation 4C);
- (b) specify what the Secretary must do when such an application is lodged (regulation 4C);
- (c) require an application fee of \$70 to be paid by the applicant to consider and process each registration or listing for which a declaration is sought (regulation 4E); and

- (d) provide for an avenue of appeal against the decision of the Secretary to refuse to make a declaration (regulation 4F).

Details of the Regulations are set out in the Attachment.

The Regulations commence on the date they are gazetted.

ATTACHMENT

Regulation 1 states that these amending regulations will be called the Therapeutic Goods (Charges) Amendment Regulations 1998.

Regulation 2 provides that the amendments commence to operate from the date these regulations are gazetted.

Regulation 3 provides that the principal regulations, the Charges Regulations, are amended as set out in these provisions.

Regulation 4 renames the Principal Regulations, to disclose the year of those Regulations. The name of the Principal Regulations will be the Therapeutic Goods (Charges) Regulations 1990.

Regulations 5 and 6 have the effect of providing for new procedures that allow applications to be made for a declaration by the Secretary that particular therapeutic goods registered or listed in the name of the applicant has a turnover that is of low volume and low value. Regulation 6 inserts new Regulations 4B, 4C, 4D, 4E and 4F.

New Regulation 4B provides that annual charges payable for maintaining every Registration or listing of therapeutic goods in the Register are not payable if the turnover for the particular goods is of low volume and low value.

New Regulation 4C sets out the process for applying for a declaration.

New subregulation 4C(1) enables a person who has therapeutic goods registered or listed in the Register to apply to the Secretary for a declaration that the turnover for particular goods is of low volume and low value.

New subregulation 4C(2) provides that an application must be in writing and the applicant must use a form approved in writing by the Secretary, and the application must be accompanied by the prescribed application fee of \$70 as provided for in propose new Regulation 4D.

New subregulation 4C(3) provides that when the Secretary receives the application, the Secretary must as soon as practicable either make a declaration or refuse the application.

New subregulation 4C(4) sets out the matters the Secretary must consider in determining whether or not turnover of the particular registered or listed therapeutic goods is of low volume and low value.

New subregulation 4C(5) requires the Secretary to make a declaration if the Secretary is satisfied that the charge for registration or listing payable, if an application is refused by the Secretary, is greater than 6% of the value of the wholesale turnover of those goods in the previous financial year to that to which the charge relates. Where there is no turnover of the goods in the previous year, then the benchmark is 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.

New Regulation 4D provides that the Secretary may delegate, in writing, his or her function to make declarations under new Regulation 4C, and a person exercising a power under that delegation is required to comply with any conditions imposed by the Secretary or directions given by the Secretary.

New Regulation 4E sets out the legislative basis for prescribing a processing fee of \$70 for considering each application for a declaration in respect of a particular registration, or particular listing, of therapeutic goods. However the maximum amount payable in any financial year by the

same applicant will be capped at \$10,000, or applications for declarations for 143 or more registered and/or listed therapeutic goods.

New regulation 4F allows an applicant to appeal to the Administrative Appeals Tribunal for a review of a decision to refuse an application for a declaration.

Regulation 7 makes a consequential amendment to correctly refer to the new paragraph 4C(4)(b) that replaces the repealed paragraph 4(2)(b).