

# **Therapeutic Goods (Charges) Amendment Regulations 2002 (No. 2) 2002 No. 235**

## **EXPLANATORY STATEMENT**

### **STATUTORY RULES 2002 No. 235**

Issued by the authority of the Parliamentary Secretary to the Minister for Health and Ageing

*Therapeutic Goods (Charges) Act 1989*

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

The object of the *Therapeutic Goods (Charges) Act 1989* (the Act) is to allow the imposition of an annual charge on the registration, listing and inclusion in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods. The Therapeutic Goods Administration is responsible for administering the Act.

Section 5 of the Act provides that the Governor-General may make regulations not inconsistent with the Act prescribing the amounts of charges.

The purpose of the Regulations is to insert the detail necessary to implement the provisions of the Act, as amended by the *Therapeutic Goods (Charges) Amendment Act 2002*, with regard to the inclusion of medical devices in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*. The Regulations specify the amount of the annual charges to be imposed in respect of the inclusion of medical devices, and make changes consequential to the new category of "included medical devices".

Details of the Regulations are set out in the Attachment.

Two related Regulations, the Therapeutic Goods (Medical Devices) Regulations 2002 and the Therapeutic Goods Amendment Regulations 2002 (No. 4), will commence operation with these Regulations.

The Regulations commence on the date of commencement of Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, ie 4 October 2002.

## ATTACHMENT 1

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

**Regulation 1** names these Regulations as the *Therapeutic Goods (Charges) Amendment Regulations 2002 (No. 2)*

**Regulation 2** specifies that these Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, ie 4 October 2002.

**Regulation 3** states that Schedule 1 amends the *Therapeutic Goods (Charges) Regulations 1990*.

#### Schedule 1 Amendments

This Schedule contains the amendments to the *Therapeutic Goods (Charges) Regulations 1990* for the purposes of regulation 3.

**Item 1** numbers the existing text of regulation 2 as new subregulation (1).

**Item 2** inserts in regulation 2 new subregulation (2) to specify that a reference to a medical device of a particular class relates to a medical device classified in accordance with the provisions of Division 3.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

**Item 3** inserts, after subregulation 3 (1A), subregulation (1B) which specifies for the purposes of subsection 4(1B) of the Act, the annual charges to be imposed in relation to the inclusion of kinds of medical devices in the Register.

**Item 4** omits the reference to Part 4 (of the *Therapeutic Goods Act 1989*) in the note to subregulation 3(3), and substitutes a reference to Part 3-3, to allow for renumbering in that Act.

**Item 5** inserts, in subregulation 4B(1), wording to extend to kinds of medical devices included in the Register the provision for non-payment of annual charges when turnover of the devices is declared to be of low volume and low value.

**Item 6** inserts, in subregulation 4C(1), a reference to "kinds of medical devices that are included in the Register" as goods for which a person who has, or expects to have turnover of low volume and low value, may apply to the Secretary for a declaration to that effect.

**Item 7** amends subregulation 4C(2)(b) so that it reads "be accompanied by the application fee under regulation 4E", rather than "... for regulation 4E".

**Item 8** adds to the references to registration and listing in subregulation 4C(5), a reference to inclusion in the Register.

**Item 9** inserts a new subregulation (6) after subregulation 4C(5), to provide that the Secretary is taken to have refused an application under paragraph (3)(b), if the applicant has not received notice of the Secretary's decision within 40 days after making the application. The insertion of this provision fulfils an undertaking to the Standing Committee on Regulations and Ordinances given by the Parliamentary Secretary on 11 March 1999 to address the Committee's concerns that regulation 4C does not provide a time limit for making a decision. This provision operates as a deemed refusal, thus allowing an application to be made for review of the decision under regulation 4F (see Item 11). Forty days is considered an appropriate timeframe to allow a proper assessment of each application.

**Item 10** clarifies that the application fee is prescribed for the purposes of paragraph 4C(2)(b).

**Item 11** inserts the provision to allow for application for review of an assumed decision to refuse an application under new subregulation 4C(6).

**Item 12** adds to subregulation 5(2), a reference to subregulations 3(1A) or (1B), for the purpose of identifying the charge payable where wholesale turnover is not regarded as low volume and low value.