

Therapeutic Goods Regulations (Amendment) 1993 No. 141

EXPLANATORY STATEMENT

STATUTORY RULES 1993 No. 141

Issued by Authority of the Minister for Family Services

Therapeutic Goods Act 1989

Therapeutic Goods Regulations (Amendment)

The Therapeutic Goods Act 1989 (the Act) has for its objective the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (TGA) has responsibility for the administration of the Act. The TGA operates from the Therapeutic Goods Administration Trust Account, established under the Audit Act 1901 and referred to in section 45 of the Therapeutic Goods Act 1989. In accordance with the Government's decision in August 1989, the TGA is required to operate on a fifty per cent cost-recovery basis, with funding raised through fees and charges collected from industry.

Section 63 of the Act provides that the Governor-General may make regulations for the purposes of the Act.

Subsections 23(2), 24(1), section 32 and paragraphs 63(2)(g) and (3)(a) of the Act enable the Governor-General to make regulations prescribing a range of application, processing or evaluation fees payable in connection with the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register) and the variation of information contained in the Register about those goods. Subsections 37(1) and 38(1) and paragraphs 63(1)(b), (2)(g) and (2)(h) of the Act enable the Governor-General to prescribe fees for processing evaluations, as well as applications for manufacturing licences and for conducting inspections of manufacturing premises and manufacturing operations used for or in connection with the manufacture of therapeutic goods.

Background

The fees and charges set out under Schedule 9 of the Therapeutic Goods Regulations and under the Therapeutic Goods (Charges) Regulations were structured with the aim of meeting the fifty per cent cost-recovery objective. However, since the Act came into operation on 15 February 1991, this objective has not been achievable with the current levels of fees and charges. This is due to a number of factors, a significant one being the very conservative approach adopted in the setting of the original level of fees and charges.

To address the shortfall in revenue, a Budget Working Party, with a membership drawn from the Australian Pharmaceutical Manufacturers Association, the Proprietary Medicines Association of Australia, the Medical Industry Association of Australia Inc, the Nutritional Foods Association and the Therapeutic Goods Administration, was set up on 20 March 1992 to canvass various options. Following meetings and considerable discussion by the group, the option of increasing fees and charges under the Act and the Therapeutic Goods (Charges) Act 1989, together with the *introduction* of new fees for new activities undertaken by TGA or for activities previously undertaken free of charge, were considered by the TGA to be the most appropriate options if the fifty per cent cost recovery objective set by government is to be met. To achieve the target fifty per cent cost recovery basis with the minimum of disruption to industry, agreement has been reached between industry and government that the increases to both fees and charges will be

phased in over a four year period, beginning with the 1993/94 financial year. Accordingly, the Regulations:

- (a) provide for the first incremental increase to a range of application fees payable for processing both applications to include therapeutic goods in the Register and applications for manufacturing licences;
- (b) increase a range of evaluation fees payable for evaluating therapeutic goods to determine their acceptability for inclusion or continued inclusion in the ARTG in accordance with criteria set out in the Act;
- (c) increase inspection fees payable for the inspection of manufacturing plants and operations undertaken by inspectors in connection with the issue of manufacturing licences or for the purposes of establishing acceptable quality of therapeutic goods;
- (d) introduce new fees for new activities undertaken by the TGA, being activities associated with processing or evaluating notifications of variations to information contained in the ARTG about therapeutic goods; and
- (e) introduce new fees for activities previously undertaken free of charge, such as evaluating the acceptability of manufacturing operations by reference to data contained in plant master files, processing applications to change data on therapeutic goods contained in the ARTG, and evaluating large amounts of data that exceed a certain number of pages.

Further details of the Regulations are set out in the Attachment.

The Regulations are to commence on 1 July 1993.

ATTACHMENT

DETAILS OF THE THERAPEUTIC GOODS REGULATIONS (AMENDMENT)

Regulation 1 provides for the Regulations to commence on 1 July 1993.

Regulation 2 provides that the Therapeutic Goods Regulations are to be amended in the manner set out in these Regulations.

Subregulation 3.1 makes a correction so that the provision in the Act referring to applications to include therapeutic goods in the Australian Register of Therapeutic Goods (the Register) is correctly referred to in Item 2 of Schedule 9. The change has been necessitated by amendments to the Act made in June 1992 which, among other things, re-numbered section 23.

Subregulations 3.2, 3.3, 3.4 and 3.6 have the effect of increasing existing application fees or introducing an application fee for processing various kinds of applications to register different categories of therapeutic goods in the Register.

Subregulations 3.5 and 3.7 have the effect of introducing lower application fees for concurrent applications to register certain drugs in the Register. Thus, under proposed new Item 2(e), where concurrent applications are lodged in respect of a Schedule 10 drug (mainly prescription drugs) and the only data required to be submitted relates to the chemistry, quality control and manufacturing information for that drug, then a fee of \$200 is applicable in respect of each concurrent application that is less than 50 pages, providing the nature of the concurrent application enables a simultaneous evaluation of the goods in the manner set out in proposed Item 2(e). Under proposed Item 2(f), a reduced application fee of \$160 (instead of the full \$300 fee currently payable) will apply to each additional concurrent application lodged to register Item 5 drugs (mainly over-the-counter drugs), where the concurrent application permits a simultaneous evaluation of the goods in the manner set out in paragraph 2(f).

Subregulation 3.8 introduces a new fee for processing requests to vary different categories of information contained in the Register concerning Schedule 10 drugs as well as over-the-counter drugs and different kinds of registrable medical devices identified in Part 1 of Schedule 3 to the Regulations.

Subregulation 3.9 makes a correction so that the right reference is made to a provision in the Act relating to applications to include goods in the Register. This correction has been necessitated by an amendment to that provision in the Act made in June 1992.

Subregulation 3.10 increases the application fee to list therapeutic goods in the Register from \$60 to \$90.

Subregulations 3.11, 3.12, 3.13, 3.14, 3.15, 3.16, 3.17, 3.18 and 3.19 increase existing evaluation fees payable for the evaluation of different classes of information relating to Schedule 10 drugs, which are in the main prescription drugs. The evaluation is conducted to determine whether the goods may be registered in the Register. **Subregulations 3.14, 3.16 and 3.19** have the effect of introducing a higher level of fees for evaluating a larger volume of data as described in those provisions.

Subregulation 3.20 increases existing evaluation fees payable for evaluating data in connection with the inclusion in the Register of mostly non-prescription drugs or payable for evaluating changes to information contained in the Register about those goods.

Subregulations 3.21 and 3.26 respectively increase existing evaluation fees payable for the evaluation of certain registrable therapeutic devices (being those set out in Part 2 of Schedule 3

to the Regulations) for the purposes of determining whether they may be included in the Register, and introduce (proposed subregulation 3.26) a new fee for evaluating information supporting a variation to data contained in the Register about such devices.

Subregulations 3.22, 3.23, 3.24 and 3.25 increase existing fees payable for the evaluation of different kinds of data relating to registrable therapeutic devices set out in Part 1 of Schedule 3 to the Regulations, for the purposes of determining whether such devices should be included in the Register.

Subregulation 3.27 clarifies that the fees set out in Item 7 of Schedule 9 apply to registrable therapeutic devices described in Part 1 of Schedule 3 to the Regulations.

Subregulations 3.28, 3.29, 3.30 and 3.31 have the effect of increasing existing evaluation fees payable for evaluating different kinds of data required to support a change to a registered therapeutic device included in the group of devices set out in Part 1 of Schedule 3 to the Regulations.

Subregulation 3.32 increases the existing application fee payable for processing an application for a manufacturing licence from \$300 to \$320.

Subregulations 3.33, 3.34, 3.35, 3.36, 3.37, 3.38, 3.39, 3.40, 3.41, 3.42, 3.43 and 3.44 increase existing inspection fees payable for the conduct of different kinds of inspections undertaken in respect of manufacturing premises or operations, for the purposes of determining whether a manufacturing licence may be issued, or for the purposes of determining whether the manufacturing and quality control procedures used in the manufacture of therapeutic goods are acceptable.

Subregulation 3.45 introduces a new fee. Proposed Item 9A relates to a new fee for the conduct of inspections to ascertain the acceptability of manufacturing operations and quality control procedures by reference to data contained in plant master files, compiled by manufacturers and which detail conditions and manufacturing procedures adopted by the manufacturer concerned.

Subregulation 3.46 provides for the application of appropriate fees, as set out under Schedule 9, for evaluation required to support a modification or variation of information in the Register relating to Schedule 10 therapeutic goods.

Subregulation 3.47 Increases the existing fee payable in respect of processing notifications of the conduct of clinical trials in Australia.

Subregulation 3.48 increases the existing fee payable for evaluating minimal data relating to therapeutic devices that require not more than half a day's work.

Subregulation 3.49 corrects a typographical error which currently has two separate items being ascribed the same number.