Therapeutic Goods Amendment Regulations 2000 (No. 4) 2000 No. 123

EXPLANATORYSTATEMENT

STATUTORY RULES 2000 No. 123

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

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2000 (No. 4)

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 exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

The Governor-General may, under section 63 of the Act, make regulations for the purposes of the Act. In particular, the Governor-General may, under subsection 63(1) and paragraphs 63(2)(h) and (3)(a), prescribe fees in respect of matters under the Act and the Regulations and in relation to different classes of goods. The Therapeutic Goods Regulations 1990 (the Principal Regulations) prescribe a range of application, processing or evaluation fees payable in connection with the processing of applications to include therapeutic goods in the Australian Register of Therapeutic Goods (the Register) or the variation of information contained in the Register about those goods.

The TGA is required to operate on a total cost recovery basis. The purpose of the Regulations is to increase some fees and reduce other fees payable under Regulation 45 and Schedule 9 of the Principal Regulations. Each set of fees relates to the performance of specific functions and the provision of services under the Act and the Regulations.

The quantum amount to be generated from the new schedule of fees in these Regulations, as well as charges imposed under the *Therapeutic Goods (Charges) Act 1989,* still falls short of the indexed 100% cost recovery figure based on the 1996-1997 50% revenue base. There is no general percentage increase across the board in the various categories of fees and charges, in some instances there is a reduction, and in other cases the proposed fees exceed the existing fees by 50% to 100%. The Medical Industry Association of Australia MAA), which is the peak industry body in relation to therapeutic devices, considered the adjustments reflected in the amending regulations provide equity across the listed and registered devices market and will give incentives for new products.

It was agreed with the N11AA that greater emphasis would be placed on annual charges rather than application and other fees as a revenue base for achieving full cost recovery.

The key changes to the fees are:

A new fee of $4000 which has been introduced for safety assessments for some listable devices. The TGA performs safety assessments for listable devices containing animal materials to ensure freedom from infectious diseases, contact lens cleaning solutions and for disinfectants making high level claims against diseases such as HIV, hepatitis C and tuberculosis.

Increases in most evaluation categories for registrable devices of between 16% and 32%. The largest evaluation fee increase (from $3690 to $10,000) is for "low level registrable devices" for instrument grade disinfectants and HIV and hepatitis C test kits used to screen the blood supply. These products require extensive multi component evaluations for effectiveness and have been

significantly under recovered in the past. On the other hand, fees for other low level registrable devices are reduced from $3690 to $3000.

Details of the Regulations are set out in the Attachment.

The Regulations commenced on gazettal.

ATTACHMENT

Therapeutic Goods Amendment Regulations 2000 (No.,1)

Regulation 1 states that the title of these regulations will be the Therapeutic Goods Amendment Regulations 2000 (No 4)

Regulation 2 provides that these regulations will commence from the date of gazettal.

Regulation 3 provides that these regulations amend the Therapeutic Goods Regulations 1990 as provided in Schedule 1.

SCHEDULE 1 - AMENDMENTS

Item 1 amends paragraph 45(4A)(a) to increase one of the discounted fees payable for processing a single application to register certain therapeutic devices, listed in Part 1 of Schedule 3 of the Regulations, in the Australian Register of Therapeutic Goods (the Register). The devices listed in Part 1 of Schedule 3 are mostly implantable devices. The discounted fee applies to the evaluation of design or testing information, or materials information. The discounted fee has been increased from $4,800 to $6,000.

Item 2 amends paragraph 45(4A)(b) to increase the discounted fee for evaluating information about the manufacture. quality control, sterile manufacture or testing of a therapeutic device described in Part 1 of Schedule 3 of the Regulations, in connection with a single application to register that therapeutic device. The discounted fee has been increased from $2,795 to 55,000.

Item 3 amends paragraph 45(4A)(c) to increase the discounted fee payable for the evaluation of either biocompatability or pre-clinical information lodged in connection with a single application to register a therapeutic device described in part 1 of Schedule 3 of the Regulations. The discounted fee has been increased from $4,190 to 55,000. Apart from the 55,000 fee payable for the evaluation of biocompatability or pre-clinical information, a separate discounted fee of $5,000 is also payable for the evaluation of any software.

Item 4 amends paragraph 45(4A)(d) to increase the discounted fee payable for the evaluation of human clinical information lodged in connection with a single application to register a therapeutic device described in Part 1 of Schedule 3 of the Regulations. The discounted fee of $16,800 has been increased to $20,000.

Item 5 amends paragraph 45(4.A)(e) to reduce the discounted fee payable for the evaluation of a confirmatory review of clinical information, from $5,640 to $5,000.

Item 6 inserts an additional discounted fee of $5,000 payable for evaluating an overseas report or data lodged by an applicant in connection with an application to register a therapeutic device that is listed in Part 1 of Schedule 3 of the Regulations. The overseas evaluation report or data is prepared by another overseas regulatory agency in relation to the device, which is lodged by an applicant to support an application to register the device in Australia. [new paragraph 45(4A)(f)l

Items 7, 8, 9 and 10 amend paragraphs 45(9)(a), (b), (c) and (d) to make adjustments to the discounted amounts payable for processing multiple applications to register a number of devices, where the multiple applications are lodged at the same time by the same sponsor of the various devices, and the information accompanying the applications is sufficiently similar to enable an evaluation of each device to be undertaken simultaneously. To qualify for the discounted fees payable under this provision all the devices must be of a kind that is listed in Part 1 of Schedule 31 of the Regulations and the sponsor must have paid the total amount of fees charged under Item 6, Schedule 9 of the Regulations for an evaluation of the principal application. The discounted fees payable relate to each additional application other than the original application, and the discounted fees relate to the evaluation of different aspects of each additional application. The evaluation of software attracts its own set of discounted fees, which are payable

in addition to any other discounted fees applying for the evaluation of different aspects of a therapeutic device described in Part 1 of Schedule 3 of the Regulations.

Item 11 inserts an additional fee that may be discounted where multiple applications to register a number of devices are simultaneously lodged by the same sponsor, as described in sub regulation 45(8). This is the fee charged for processing an application that includes an evaluation report or data, prepared by another overseas regulatory agency in relation to the particular device, which is lodged by an applicant to support its applications to register that device in Australia. The discounted fee is payable in relation to each additional application that is lodged by the same sponsor. [new paragraph 45(9)(e)]

Items 12, 13, 14 and 15 amend paragraphs 45(11)(a), (b), (c) and (d) to make adjustments to the discounted amounts payable for processing multiple applications to vary information about more than one device already included in the Register, where the multiple applications are lodged at the same time by the same sponsor of the various devices, and the information accompanying the applications is sufficiently similar to enable an evaluation of each device to be undertaken simultaneously. To qualify for the discounted fees payable under this provision all the devices must be of a kind that is listed in Part 1 of Schedule 3, and the applicant must have paid the full evaluation fee in relation to one of the applications to vary information about a device included in the Register. The discounted fees payable relate to each additional application to vary information, other than the principal application, about a number of devices and the discounted fees relate to the evaluation of different aspects of each additional application. The evaluation of software attracts its own set of discounted fees, and is payable in addition to any other discounted fees applying for the evaluation of different aspects of a therapeutic device described in Part 1 *of Schedule 3 of the Regulations.

Item 16 inserts an additional fee that may be discounted where multiple applications to vary information about various devices are simultaneously lodged by the same sponsor, as described in subregulation 45(10). This is the fee charged for processing an application that includes an evaluation report or data, prepared by another overseas regulatory agency in relation to the particular device, which is lodged by an applicant to support its applications to vary information about a device included in the Register. The discounted fee is payable in relation to each additional application that is lodged by the same sponsor. [new paragraph 45(11)(e)l

Item 17 inserts a new fee for processing an application seeking approval to import, export or manufacture therapeutic goods (not just therapeutic devices) for supply to humans that do not conform to a standard applicable to those goods. [Item 1 A of Schedule 91

Item 18 does not alter the substance of Item 2(c) of Schedule 9, but merely seeks to clarify that the fee payable under Item 2(c) relates to an application to register a device that is described in Part 1 of Schedule 3 of the Regulations, unless multiple applications are involved in which case different fees may apply.

Items 19 and 20 amend subparagraph (d)(ii) and paragraph (d) of Item 2 of Schedule 9 to correct punctuation and omit words that have been made redundant by the insertion of words set out in **Item 21.**

item 21 amends Schedule 9, Item 2, subparagraph (d)(ii), column 3 to clarify that there is an upper limit to the amount of application fees payable by a sponsor who lodges multiple applications to register, among other things, a number of therapeutic devices. For each additional application to register (excluding the 4coriginal" application) that qualifies under Item 2(d)(i) of Schedule 9 of the Regulations, the application fee payable will be $1,200, however the total amount payable for all applications lodged for the purposes of s.23(2)(a) of the Act must not exceed a total of $7.000. The amount of $7,000 includes any application fee that is paid for lodging the initial application to register a device listed in Part 1 of Schedule 3 of the Regulations.

Item 22 amends Item 5A of Schedule 9 by replacing the current evaluation fee payable for the evaluation of therapeutic devices listed in Part 2 of Schedule 3. These are in the main devices

that are non-implantable. The new fees specify different fees that are payable for the evaluation of different aspects of an application, such as design or materials information or testing data, of information about biocompatability or clinical information. **Item 22** also inserts a new fee, item 5B of Schedule 9. for the evaluation of disinfectants or diagnostic goods for in vitro use.

Item 23 sets out the separate and new evaluation fee payable to evaluate an application to vary information about different therapeutic devices listed under Part 2 of Schedule 3, being a device that is already included in the Register. The new fees are set out in Items 6A and 613 of Schedule 9.

In addition, a new Item 6C has been inserted which requires a fee of $4,000 to be paid for the evaluation of information submitted pursuant to paragraph 31(2)(f) of the Act, being information about the safety of listable therapeutic goods (not just listable therapeutic devices) for the purposes for which they are to be used. This information may be required when an application is lodged to list therapeutic goods in the Register, or the information may be required in relation to listable therapeutic goods already included in the Register.

Item 24 inserts a new fee for the evaluation of overseas reports or data submitted by a sponsor in support of an application to vary or amend information about a registered therapeutic device, described in Part 1 of Schedule 3 of the Regulations, included in the Register. [Schedule 9, item 7, paragraph **(f)l**

Item 25 inserts a new fee for work undertaken to establish whether a listable therapeutic device is safe for the purposes for which it is to be used. This assessment is undertaken in the context of an application to include the device in the Register. [Item 9B of Schedule 91

Item 26 amends Item 14A of Schedule 9 to reduce the fee currently payable by a person giving notice of an intention to sponsor a clinical trial in accordance with Item 3 of Schedule 5 A of the Regulations.

Item 27 sets out a list of changes to existing fees payable under Schedule 9 in relation to the processing of applications to include therapeutic devices in the Register or to vary information about therapeutic devices already included in the Register. Most of the changes effect an increase to existing fees, there are a few that reduce current fees. All the adjustments have been made to more accurately reflect the cost of performing the relevant functions and activities under the Act and the Regulations.