EXPLANATORY STATEMENT

Select Legislative Instrument 2007 No. 162

Subject - *Therapeutic Goods (Charges) Act 1989*

Therapeutic Goods (Charges) Amendment Regulations 2007 (No. 1)

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 of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Subsection 5(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing the amounts of charges. Subsection 5(2) enables the Governor-General to prescribe different levels of charges for different classes of goods or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

The purpose of the Regulations is to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Principal Regulations) to increase all charges by 4.0 per cent (the increase applies to annual charges to goods that may be either registered, listed or included on the Register, and all types of manufacturing licences that are in force at any time during the financial year).

Except for medical devices, therapeutic goods are generally required to be either registered or listed on the Register before being imported into, exported from, supplied or manufactured in Australia. Therapeutic goods assessed as having a higher level of risk (such as prescription medicines, and some non-prescription medicines) are evaluated by the TGA for quality, safety and efficacy and are registered on the Register. Therapeutic goods having a lower risk (generally, consumer medicines purchased over the counter such as complementary medicines, including vitamins) are assessed by the TGA for quality and safety but not efficacy (meaning the TGA has not evaluated such products individually) and are listed on the Register. Medical devices are not categorised as “registered” or “listed” based on level of risk, as medicines. Medical devices are graded into several classes (for example, Classes I, IIa, IIb, III and AIMD (active implantable medical devices)) to reflect level of risk, and generally all classes are still required to be “included” in the Register before being imported into, exported from, supplied or manufactured in Australia.

Section 4 of the Act provides that annual charges of such amounts as are prescribed are payable for maintaining entries of therapeutic goods in the Register. Subsection 4(1A) of the Act provides that where one or more therapeutic goods are “grouped” and each of the “grouped” therapeutic goods is covered by a single registration or listing number, then an annual charge as prescribed will apply for maintaining all the registered or listed goods covered under the same grouping. A single charge has been prescribed for this purpose.

However, the Regulations also include exceptions to the general 4.0 per cent increase, which will:

- increase the annual charges that are payable for maintaining the registration of a prescription medicine by 17 per cent (this change relates to prescription medicines that are registered on the Register); and
- decrease by $220 (to $480) the annual charges that are payable for Class 1 medical devices which are supplied in a sterile state or have a measuring function to differentiate the amount of work relative to a Class II medical device (specifically, indicators suggest that the surveillance and problem incidence is lower than Class IIa and IIb medical devices) (this change relates to medical devices that are registered on the Register).

The annual charges for Class 1 medical devices, listable goods and non prescription medicines remain unchanged (the latter relates to goods that may be either registered or listed on the Register).

The new charges have been rounded to the nearest ten dollars (for amounts up to ten thousand dollars) or one hundred dollars (for amounts of ten thousand dollars or more). An exception to the rounding is the charge increase noted at item [4] of Schedule 1 to the Regulations. This change increases the charge for making an application in relation to paragraph 4C(2)(b) of the Principal Regulations (an application for a declaration that the person making the application has low volume and low value turnover of particular registered or listed therapeutic goods or kinds of medical devices) from $110 to $120. The charge increase in relation to paragraph 4C(2)(b) has been made because, if the rounding policy were applied strictly in the case of a 4.0 per cent increase to the current charge of $110, the resulting amount ($114.40) would have to revert to its current level.

The Regulations, when taken together with the changes to the *Therapeutic Goods Regulations 1990*, and the *Therapeutic Goods (Medical Devices) Regulations 2002* (which are the subject of separate Executive Council Minutes), are expected to increase the fees and charges collected by the TGA by $5.542 million over the 2007-2008 financial year.

The increases in charges enable the TGA to recover its costs in administering the *Therapeutic Goods Act 1989* and continue to meet the Government's requirement that the TGA operate on a full cost-recovery basis.

An overview of the Regulations is at Attachment A, and details are set out in Attachment B.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations commence on 1 July 2007.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT A

OVERVIEW OF THE *THERAPEUTIC GOODS (CHARGES) AMENDMENT REGULATIONS 2007 (NO. 1)*

The Regulations introduce a 4.0 per cent general (composite) increase in relation to all other annual charges applicable under the Principal Regulations. This applies for maintaining listings, registrations or inclusions of a kind of medical device on the Register, and all types of manufacturing licences. The general composite increase has been calculated using a formula agreed with industry associations which is comprised of 50 per cent of the annual Wage Cost Index (WCI) for the year ended December 2006 and 50 per cent of the Consumer Price Index (CPI) for the year ended December 2006.

The Regulations also increase the annual charges for maintaining the registration of prescription medicines by 17 per cent. This is in line with a plan agreed with the pharmaceutical industry in July 2003 to restructure the fee schedule to better reflect the underlying cost of regulatory activities performed by the TGA. Regulations that reduce evaluation fees for most prescription medicines by up to 4.5 per cent as part of that fees restructuring plan are the subject of a separate Executive Council Minute. The overall change in total cost recovery for prescription medicines will be an increase of around 7.5 per cent.

Exclusions from the general (composite) increase are the annual charges for listed medicines ($690) and Class 1 medical devices ($60) which will remain unchanged; and the annual charges for Class I medical devices which are supplied in a sterile state or have a measuring function which decrease by $220 (from $700 to $480) to differentiate the amount of work relative to Class II medical devices (specifically, indicators suggest that the surveillance and problem incidence is lower than Class IIa and IIb medical devices).

The Regulations also include a technical amendment to amend the note to subregulation 3(3) of the Principal Regulations to ensure that it is consistent with regulations amending the *Therapeutic Goods Regulations 1990* (which are the subject of a separate Executive Council Minute). Regulations amending the *Therapeutic Goods Regulations 1990* will amend the title heading of regulation 45, and subregulation 45(1), of those Regulations to increase the low turnover threshold at which the annual charge for a licence to manufacture therapeutic goods is reduced, for a person required to hold such a licence, from $68,300 to $71,000. The note to subregulation 3(3) of the Principal Regulations refers to the current low turnover threshold of $68,300 and, accordingly, needs to be changed to ensure consistency across the two sets of regulations.

The new charges have been rounded to the nearest ten dollars (for amounts up to ten thousand dollars) or one hundred dollars (for amounts of ten thousand dollars or more). An exception to the rounding is the charge increase noted at Item [4] to the Regulations. This change increases the charge for making an application in relation to paragraph 4C(2)(b) of the Principal Regulations (an application for a declaration that the person making the application has low volume and low value turnover of particular registered or listed therapeutic goods or kinds of medical devices) from $110 to $120. The charge increase in relation to paragraph 4C(2)(b) has been made because, if the rounding policy were applied strictly in the case of a 4.0 per cent increase to the current charge of $110, the resulting amount ($114.40) would have to revert to its current level.

Generally, significant changes to regulatory arrangements of new regulatory proposals involve additional consultation with affected sectors and result in the preparation of Cost Recovery Impact Statements (CRIS). A CRIS ensures that the TGA's cost recovery arrangements are consistent with the Government's Cost Recovery Guidelines for Regulatory Agencies issued in December 2002. The last full review of TGA's cost recovery arrangements were undertaken in May 2005 and a CRIS was prepared. Subsequent CRIS' have examined arrangements for the regulation of in-vitro diagnostic devices (March 2006); and the increases to annual charges for non prescription medicines (June 2006).

In administering the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Charges) Act 1989*, the TGA collects fees and charges prescribed in these Acts from persons and companies involved in the supply, import, export and manufacture of therapeutic goods in Australia.

The TGA consulted with industry associations, including Medicines Australia, the Generic Medicines Industry of Australia, the Australian Self-Medication Industry, the Complementary Healthcare Council of Australia, the Medical Industry Association of Australia, the Australian Dental Industry Association and AusBiotech on the increases to charges. The consultations, convened between 13 and 23 February 2007, consisted of bilateral engagement with industry sectors and provided an opportunity for industry associations to examine and comment on the TGA Budget, including new initiatives and other budget measures, and on the annual charges. The outcome of the consultations was that industry was generally supportive of the TGA proposals for 2007-08 annual charges.

As the recommended increases are in line with the indexation rate agreed with industry associations, a cost recovery impact statement is not required.

ATTACHMENT B

DETAILS OF THE *THERAPEUTIC GOODS (CHARGES) AMENDMENT REGULATIONS 2007 (NO. 1)*

Regulation 1 provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment Regulations 2007 (No. 1).*

Regulation 2 provides for the Regulations to commence on 1 July 2007.

Regulation 3 provides for Schedule 1 to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Principal Regulations).

Schedule 1 - Amendments

Item [1]
Subregulation 3(1B) of the Principal Regulations currently provides, for the purposes of subsection 4 (1B) of the Act, that the annual charges in respect of the inclusion of kinds of medical devices (other than medical devices produced for export) in the Register under Chapter 4 of the *Therapeutic Goods Act 1989* that has effect at any time during a financial year are as follows:

(a) for a Class I medical device (other than a Class I medical device to which (b) applies) - $60;
(b) for a Class IIb medical device, Class IIa medical device, or Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function - $700;
(c) for a Class AIMD medical device or Class III medical device - $920

The purpose of this item is to separate Class IIb and Class IIa medical devices from Class I medical devices which the manufacturer intends to be supplied in a sterile state or that has a measuring function, in paragraph 3(1B)(b) of the Principal Regulations to differentiate the amount of work relative to a Class II medical device. Indicators suggest that the surveillance and problem incidence is lower for Class 1 medical device than Class IIa and IIb medical devices.

Specifically, this item deletes “for a Class IIb medical device, Class IIa medical device, or Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function - $700” from paragraph 3(1B)(b) and replaces it with “for a Class 1 medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function - $480”. The annual charge applicable, in paragraph 3(1B)(b) decreases by $220 (to $480);

This item amends Paragraph 3(1B)(c) by replacing “for a Class AIMD medical device or Class III medical device - $920” with “for a Class IIb medical device, or Class IIa medical device - $730”. The annual charge applicable in paragraph 3(1B)(c) increases by 4.0 per cent.

This item inserts a new paragraph 3(1B)(d) "for a Class AIMD medical device or Class III medical device - $960". The annual charge applicable in paragraph 3(1B)(d) increases the current fee by 4.0 per cent.

This item makes no change to the charge applicable, respectively in paragraph 3(1B)(a).

Item [2]
Subregulation 45A(1) of the *Therapeutic Goods Regulations 1990* currently provides that the annual charges for a licence payable by a person are reduced if the wholesale turnover of therapeutic goods is less than $68,300. Regulations that increase the low turnover threshold by 4.0 per cent, to $71,000, are the subject of a separate Executive Council Minute. The note to subregulation 3(3) of the Principal Regulations currently refers to the $68,300 threshold. This item amends the note to subregulation 3(3) so that it refers to the new $71,000 threshold.

Item [3]
This item increases all annual charges (except the annual charges for listed non prescription medicines and Class I medical devices which will remain unchanged), applicable in subparagraphs 3(1)(a)(i), 3(1)(a)(ii), 3(1)(a)(iii), 3(1)(c)(ii), 3(1)(c)(iii), 3(1A)(a)(i), 3(1A)(a)(ii), 3(1A)(a)(iii), 3(1A)(c)(ii), 3(1A)(c)(iii), 3(2)(j)(i), 3(2)(j)(ii), and paragraphs 3(2)(a) and (b), 3(2)(c) to (h), 3(2)(ja) and (k), and 3(2)(l) of the Principal Regulations, by 4.0 per cent.

This item also increases the annual charges for registered prescription medicines, applicable in subparagraphs 3(1)(b)(i), 3(1)(b)(ii), 3(1A)(b)(i), and 3(1A)(b)(ii) of the Principal Regulations by 17 per cent. This is in line with the plan to restructure the fee schedule agreed with stakeholders in July 2003. The plan aims to reduce overall cost recovery from pre-market fees and increase the proportion of cost recovery for post-market activities through annual charges. Evaluation fees for prescription medicines will be reduced under the restructuring plan.

These increases enable the TGA to recover its costs in administering the Act and continue to meet the Government's requirement that the TGA operate on a full cost-recovery basis.

Item [4]
This item, by amending subregulation 4E(1) of the Principal Regulations, increases the fee for making an application in relation to paragraph 4C(2)(b) of the Principal Regulations from $110 to $120.

Under subregulation 4C(1) of the Principal Regulations, a person who has, or expects to have, low volume and low value turnover of particular registered or listed therapeutic goods or kinds of medical devices, may apply to the Secretary of the Department of Health and Ageing for a declaration to that effect.

The effect of a declaration of the Secretary under regulation 4C is that, as subregulation 4B(1) of the Principal Regulations provides, annual charges in respect of the registration or listing of therapeutic goods, or the inclusion of the kinds of medical devices in the Register under Chapter 4 of the *Therapeutic Goods Act 1989*, are not payable by persons whose turnover of those goods or devices is declared under regulation 4C to be of low volume and low value.

This item also increases the threshold for the maximum amount payable in subregulation 4E(2) of the Principal Regulations by 4.0 per cent, from $11,900 to $12,400. Subregulation 4E(2) currently provides that if the total amount of application fees incurred by an applicant in a year reaches $11,900, the applicant is not required to pay all or part of an application fee for any more applications made in the year.

These increases enable the TGA to recover its costs in administering the Act and continue to meet the Government's requirement that the TGA operate on a full cost-recovery basis.