

EXPLANATORY STATEMENT

Select Legislative Instrument 2006 No. 213

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 2006 (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.

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 in 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 and III) 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.

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* to increase:

- the annual charges that are payable for maintaining the registration of a prescription medicine by 20 per cent (this change relates to prescription medicines that are registered on the Register);

- the annual charges that are payable for maintaining the entry in the Register of both listed and registered non-prescription medicines by \$150 (this change relates to non-prescription medicines that are listed or registered on the Register); and
- all other annual charges set out in the *Therapeutic Goods (Charges) Regulations 1990* (except the annual charge for class 1 medical devices which remains unchanged) in line with a general (composite) increase of 3.5 per cent (this change relates to goods that may be either registered, listed or included on the Register).

The increases in charges will 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 the day after they are registered on the Federal Register of Legislative Instruments.

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 2006 (NO. 1)**

The Regulations increase the annual charges for maintaining the registration of prescription medicines by 20 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 will reduce evaluation fees for most prescription medicines by up to 3.1 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 around 3.5 per cent.

The Regulations increase annual charges for both listed and registered non-prescription medicines by \$150, to \$690 and \$880 respectively, to curtail persistent under recovery of costs over recent years. The increases (which constitute a 28 per cent increase for listed non-prescription medicines and a 20 per cent increase for registered non-prescription medicines) are in excess of the consumer price index and represent a material amendment of an existing cost recovery arrangement. A Cost Recovery Impact Statement incorporating stakeholder views in relation to these changes was completed in May 2006 in accordance with Australian Government Cost Recovery Guidelines and has been published on the TGA's website.

The Regulations also introduce a 3.5 per cent general (composite) increase in relation to all other annual charges applicable under the *Therapeutic Goods (Charges) Regulations 1990*. This will apply 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 2005 and 50 per cent of the Consumer Price Index (CPI) for the year ended December 2005.

An exclusion from the general (composite) increase is the annual charge for class 1 medical devices which will remain unchanged at \$60, having been increased by \$10 in the previous year.

The Regulations amend the note to subregulation 3(3) of the *Therapeutic Goods (Charges) Regulations 1990* 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* amend the title 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 \$66,000 to \$68,300. The note to subregulation 3(3) of the *Therapeutic Goods (Charges) Regulations 1990* refers to the current low turnover threshold of \$66,000 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 dollar (for amounts up to ten thousand dollars) or one hundred dollar (for amounts of ten thousand dollars or more) increments, except for the fee increase noted at Item [26]. This change increases the fee 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 \$100 to \$110. The fee increase in relation to paragraph 4C(2)(b) has been made because, if the rounding policy were applied strictly in the case of a 3.5 per cent increase to the current fee of \$100, the resulting amount (\$103.50) would have to revert to its current level.

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, including (as noted above), undertaking a Cost Recovery Impact Statement in accordance with Australian Government Cost Recovery Guidelines in relation to the increases, which has been published on the TGA's website.

ATTACHMENT B**DETAILS OF THE *THERAPEUTIC GOODS (CHARGES) AMENDMENT REGULATIONS 2006 (NO. 1)***

Regulation 1 provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment Regulations 2006 (No. 1)*.

Regulation 2 provides for the Regulations to commence on the day after they are registered.

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

Schedule 1 - Amendments**Items [1] and [9]**

These items increase annual charges for registered non-prescription medicines, applicable, respectively, in subparagraphs 3(1)(a)(i) and 3(1A)(a)(i) of the Principal Regulations, by \$150 (20 percent). This will curtail persistent under-recovery of costs from industry over recent years. A Cost Recovery Impact Statement incorporating stakeholder views has been completed in accordance with Australian Government Cost Recovery Guidelines and has been published on the TGA's website.

Items [4], [5], [12] and [13]

These items increase the annual charges for registered prescription medicines, applicable, respectively, in subparagraphs 3(1)(b)(i), 3(1)(b)(ii), 3(1A)(b)(i), and 3(1A)(b)(ii) of the Principal Regulations by 20 per cent. This is in line with a 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.

Items [6] and [14]

These items increase annual charges for listed non-prescription medicines, applicable, respectively, in subparagraphs 3(1)(c)(i) and 3(1A)(c)(i) of the Principal Regulations, by \$150 (28 per cent). This will curtail persistent under-recovery of costs from industry over recent years. A Cost Recovery Impact Statement incorporating stakeholder views has been completed in accordance with Australian Government Cost Recovery Guidelines and has been published on the TGA's website.

Item [26]

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 \$100 to \$110.

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 increase enables 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 [27]

This item increases the threshold for the maximum amount payable in subregulation 4E(2) of the Principal Regulations by 3.5 per cent, from \$11,500 to \$11,900. Subregulation 4E(2) currently provides that if the total amount of application fees incurred by an applicant in a year reaches \$11,500, the applicant is not required to pay all or part of an application fee for any more applications made in the year. This increase enables 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.

Items [2], [3], [7], [8], [10], [11] and [15] to [24]

These items increase all annual charges other than those noted above (and except the annual charge for class 1 medical devices which remains unchanged), applicable, respectively in subparagraphs 3(1)(a)(ii), 3(1)(a)(iii), 3(1)(c)(ii), 3(1)(c)(iii), 3(1A)(a)(ii), 3(1A)(c)(ii), 3(1A)(c)(iii), 3(2)(j)(i), 3(2)(j)(ii), and paragraphs 3(1B)(b), 3(1B)(c), 3(2)(a) and (b), 3(2)(c) to (h), 3(2)(ja) and (k), and 3(2)(l) of the Principal Regulations, by 3.5 per cent. This increase enables 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 [25]

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 \$66,000. Regulations that increase the low turnover threshold by 3.5 per cent, to \$68,300, are the subject of a separate Executive Council Minute. The note to subregulation 3(3) of the Principal Regulations currently refers to the \$66,000 threshold. This item amends the note to subregulation 3(3) so that it refers to the new \$68,300 threshold.