

EXPLANATORY STATEMENT

Select Legislative Instrument 2011 No. 103

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 2011 (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 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.

Section 4 of the Act provides that annual charges of such amounts as are prescribed are payable in respect of entries of therapeutic goods (including medical devices) in the Register, as well as in respect of licences that are in force at any time within a financial year. Under subsection 4(1A) of the Act, 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 a single annual charge as prescribed will apply for maintaining all the registered or listed goods covered under the same group.

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) of the Act 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 annual product charges for medicines, medical devices and other therapeutic goods and for licences by 3.4 per cent.

The 3.4 per cent increase is a general composite increase that has been calculated using a formula agreed between the TGA and industry associations, which is comprised of 50 per cent of the Labour Price Index from September 2009 to September 2010 and 50 per cent of the Consumer Price Index for the same period. The annual product charges were last increased in July 2010.

The new charges have been rounded to the nearest \$10 for amounts below \$10,000 or \$100 for amounts of \$10,000 or more.

As a result of the TGA’s rounding policy, the annual charge for the inclusion of a Class I medical device referred to in paragraph 3(1B)(a) of the Principal Regulations remains unchanged at \$60.

The increase to charges, when taken together with increases to fees in the changes to the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002* (which are the subject of a separate Minute), are expected to increase the total of fees and charges collected by the TGA by \$3.5 million to \$118.3 million in the 2011-12 financial year.

The increase in charges enable the TGA to recover its costs in administering the *Therapeutic Goods Act 1989* and to continue to meet the Government's Cost Recovery Guidelines.

The Regulations also include a minor amendment to amend paragraph 3(2)(j) of the Principal Regulations to ensure that the annual charge for a manufacturing licence in relation to a fixed (non-mobile) site where human blood and blood components (other than haematopoietic progenitor cells) are manufactured will continue to apply to such sites whether or not they are associated or linked with a primary site. This change ensures that the Principal Regulations properly reflect changes made to the Therapeutic Goods Act in 2010 made by the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009* replacing most multi-site manufacturing licences with single site licences.

Details of the Regulations are set out in the Attachment.

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

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

The Regulations commence on 1 July 2011.

Consultation

The TGA consulted with industry on its 2010-11 financial forecast and outlook for financial year 2011-12 in bilateral meetings held between 16 and 25 February 2011. These meetings provided an opportunity for industry to present relevant information to be taken into account as part of the TGA's assessment and estimate of its regulatory workload and costs for financial year 2011-12.

The TGA and industry associations agreed in the past to use an indexation model to adjust fees and charges annually (with additional increases to be justified to industry), in line with cost and wage movements in the public sector. That indexation model is comprised of 50 per cent of the Australian Bureau of Statistics' wage-cost index, which reflects average wage cost movements, and 50 per cent of the Consumer Price Index. The 3.4 per cent increase in annual product charges and annual charges for manufacturing licences that are effected by the Regulations are consistent with the TGA-industry agreement on increases to fees and charges.

The amendment to paragraph 3(2)(j)(ii) of the Principal Regulations ensures that the annual charge for a manufacturing licence in relation to a fixed (non-mobile) site where human blood and blood components (other than haematopoietic progenitor cells) are manufactured will continue to apply to such sites whether or not they are associated or linked with a primary site (being, the principal premises in each State and Territory capital city where such products are manufactured) was not consulted with industry as it is minor and machinery in nature.

DETAILS OF THE *THERAPEUTIC GOODS (CHARGES) AMENDMENT REGULATIONS 2011 (NO. 2)*

Regulation 1 – Name of Regulations

This regulation provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment Regulations 2011 (No. 2)*.

Regulation 2 - Commencement

This regulation provides for the Regulations to commence on 1 July 2011.

Regulation 3 – Amendment of *Therapeutic Goods (Charges) Regulations 1990*

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

Schedule 1 - Amendments

Item [1] – Subparagraph 3(2)(j)(ii)

Paragraph 3(2)(j) of the Principal Regulations currently provides that the applicable annual charges for manufacturing licences for the manufacture of human blood and blood components (other than haematopoietic progenitor cells) at manufacturing premises covered by the licence are, for a primary site, \$128,700, and for each additional fixed (non-mobile) manufacturing site associated with the primary site, \$6,330. “Primary site” is defined in subregulation 3(4) of the Principal Regulations as the principal premises in the capital city of each State and Territory where human blood and blood components are manufactured.

Following the commencement in February 2010 of measures introduced to the *Therapeutic Goods Act 1989* by the *Therapeutic Goods (2009 Measures No. 1) Act 2009* to replace multi-site manufacturing licences with predominantly single site licences, many fixed (non-mobile) sites manufacturing human blood and blood components are no longer “associated with” the primary site in their State or Territory for the purposes of paragraph 3(2)(j).

Item [1] therefore replaces the current paragraph 3(2)(j)(ii) of the Principal Regulations with a new paragraph 3(2)(j)(ii) which does not refer to an association with a primary site.

This change has the effect of ensuring that the annual charge set out at subparagraph 3(2)(j)(ii) of the Principal Regulations applies to fixed (non mobile) sites for the manufacture of human blood and blood components (other than haematopoietic progenitor cells), whether or not such sites are covered by a single site manufacturing licence or by a multi site licence in conjunction with a primary site.

Item [2] – Subregulation 3(3), note

The note to subregulation 3(3) of the Principal Regulations refers to the fact that under regulation 43AAJ of the *Therapeutic Goods Regulations 1990* the annual charge for a licence under Part 3-3 of the *Therapeutic Goods Act* (other than a licence for the manufacture of human blood and blood components) payable by a person whose wholesale turnover of therapeutic goods in a financial year is not more than \$78,600 is half the amount mentioned in subregulation 3(2) for the person.

Item [2] replaces the reference to the amount of \$78,600 in the note with a reference to the amount of \$81,300.

This change has the effect of reflecting that the amount referred to in the note is increased by 3.4 per cent to \$81,300 as part of amendments to the Therapeutic Goods Regulations that are the subject of a separate Minute.

Item [3] – Further amendments

This item increases all annual charges for therapeutic goods and manufacturing licences set out in the Principal Regulations by 3.4 per cent except for the annual charge for the inclusion in the Register of a Class I medical device referred to in paragraph 3(1B)(a) of the Principal Regulations.

The annual charge for a medical device referred to in paragraph 3(1B)(a) (Class I medical devices other than those intended by its manufacturer to be supplied in a sterile state or which has a measuring function) remains unchanged at \$60 as the TGA's rounding policy rounds amounts below \$10,000 to the nearest \$10.