EXPLANATORY STATEMENT

Select Legislative Instrument 2010 No. 131

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 2010 (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.

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 charges for therapeutic goods and manufacturing licences by 2.4 per cent.

The 2.4 per cent increase is a general composite increase that has been calculated using a formula agreed between the TGA and industry associations. The annual charges in the Principal Regulations were last increased in July 2009 and the increase is comprised of 50 per cent of the Labour Price Index from September 2008 to September 2009 and 50 per cent of the Consumer Price Index from September 2008 to September 2009.

The increases to charges set out in the Regulations 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 (other than a Class I medical device intended by its manufacturer to be supplied in a sterile state or that has a measuring function), referred to in paragraph 3(1B)(a) of the Principal Regulations remains unchanged at $60.

The amendments to the Principal Regulations, when taken together with 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 fees and charges collected by the TGA by $2.4 million (to $102.9 million) over the 2010-11 financial year.

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

Details of the Regulations are set out in the Attachment.

The TGA consulted with industry on the 2009-10 financial forecast and outlook for financial year 2010-11 in bilateral meetings held in February 2010. 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 2010-11.

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 movements, and 50 per cent of the Consumer Price Index. The 2.4 per cent increase in fees and charges that would be effected by the Regulations would be consistent with the TGA-industry agreement on increases to fees and charges.

A regulatory impact statement (RIS) was not prepared in relation to the Regulations, and the Office of Best Practice Regulation confirmed that as the proposed amendments would have a no to low regulatory impact on business or individuals, a RIS was not required.

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 2010.

ATTACHMENT

DETAILS OF THE *THERAPEUTIC GOODS (CHARGES) AMENDMENT REGULATIONS 2010 (NO. 1)*

Regulation 1 – Name of Regulations
This regulation provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment Regulations 2010 (No. 1).*

Regulation 2 - Commencement
This regulation provides for the Regulations to commence on 1 July 2010.

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] – Paragraph 3(1B)(d)
This item replaces a full stop with a semi-colon after paragraph 3(IB)(d), in order to add a new paragraph 3(IB)(e) (see item [2] below).

Item [2] – After paragraph 3(1B)(d)
This item sets an annual charge for an IVD medical device at a nil amount. This reflects a commitment given to industry by the TGA not to introduce annual charges for the inclusion of IVD medical devices in the Australian Register of Therapeutic Goods until 1 July 2014. Under subsection 4 (7) of the *Therapeutic Goods (Charges) Act 1989*, an amount that may be specified as an annual charge includes a nil amount.

Item [3] – Subregulation 3(3), note
This item substitutes the note to subregulation 3 (3) of the Principal Regulations with a new note.

Subregulation 3(3) of the Principal Regulations provides that if, but for subregulation 3(3), more than one charge mentioned in subregulations 3(1) or 3(2) of the Principal Regulations otherwise applies in a financial year in relation to the registration or listing of particular therapeutic goods or a particular license, only the greatest of those charges applies.

The note at subregulation 3(3) currently sets out that under subregulations 45A(1) and 45A(2) of the *Therapeutic Goods Regulations 1990* (the TG Regulations), the annual charge for a manufacturing licence under Part 3-3 of the *Therapeutic Goods Act 1989* that is payable by a person whose wholesale turnover of therapeutic goods in a financial year is not more than $76,800 is half the amount the person is otherwise required to pay under subregulation 3(2) of the Principal Regulations, but that this does not apply in the case of a licence for the manufacture of human blood and blood components.

As a result of changes made to the TG Regulations by the *Therapeutic Goods Amendment Regulations 2009 (No.3)*, the reduction of annual charges for a manufacturing licence is now dealt with in regulation 43AAJ (not 45A) of the TG Regulations.

The new note therefore refers to new subregulations 43AAJ(1) and 43AAJ(2), rather than subregulations 45A(1) and 45A(2) of the TG Regulations.

The new note also refers to a new threshold amount of $78,600 to ensure consistency with changes to the TG Regulations (which are the subject of a separate Executive Council Minute).

Item [4] – Further amendments

This item increases all annual charges for therapeutic goods and manufacturing licences set out in the Principal Regulations by 2.4 per cent except for the annual charge for the inclusion of a Class I medical device other than a Class I medical device intended by its manufacturer to be supplied in a sterile state or which has a measuring function, 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) remains unchanged at $60 as the TGA's rounding policy rounds amounts below $10,000 to the nearest $10.