EXPLANATORY STATEMENT

Select Legislative Instrument 2010 No. 130

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2010 (No. 3)

Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 2)

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety and 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.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to increase certain fees in the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) by 2.4 per cent.

The fees increased in the TG Regulations apply to application fees for registration or listing on the Australian Register of Therapeutic Goods (the Register), application fees for manufacturing licences, evaluation fees, clinical trial notification fees, application fees for export certificates and inspection fees for manufacturing premises.

The fees increases in the MD Regulations apply to fees relating to conformity assessments and abridged conformity assessments of medical devices, applications for inclusion of medical devices in the Register and conformity assessment certificates for medical devices.

The 2.4 per cent increase of fees is a general composite increase that has been calculated using a formula agreed between the TGA and industry associations. The fees in the TG Regulations and the MD 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 fees prescribed in both sets of Regulations have been rounded to the nearest $10 for amounts less than $10,000 and to the nearest $100 for amounts greater than $10,000. As a result of this rounding policy, fee items that are $200 or less do not change.

The amendments to the TG Regulations and the MD Regulations, when taken together with changes to the Therapeutic *Goods (Charges) Regulations 1990* (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 increases enable the TGA to recover its costs in administering the Act and continue to meet the Government's Cost Recovery Guidelines.

Details of the amendments to the TG Regulations are set out in Attachment A and details of the amendments to the MD Regulations are set out in Attachment B.

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 legislative instruments for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on 1 July 2010.

ATTACHMENT A

DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2010 (No. 3)*

Regulation 1 – Name of Regulations
This regulation provides for the Regulations to be referred to as the *Therapeutic Goods Amendment Regulations 2010 (No. 3)*.

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

Regulation 3 – Amendment of *Therapeutic Goods Regulations 1990*
This regulation provides for Schedule 1 to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations).

Schedule 1 –Amendments

Item [1] – Regulation 43AAJ, heading
Subregulation 43AAJ(1) of the TG Regulations currently provides that the annual charge payable by a person required to hold a manufacturing licence under Part 3-3 of the 1989 Act and whose turnover of therapeutic goods is not more than $76,800 in a financial year, is reduced in the manner described in subregulation 43AAJ(2).

Item [3] (below) amends paragraph 43AAJ(1)(b) to increase the threshold amount of $76,800 by 2.4 per cent (subject to the TGA's rounding policy) to $78,600.

Accordingly, this item amends the heading of regulation 43AAJ to reflect that increase.

Item [2] – Regulation 45A, heading
Regulation 45A of the TG Regulations provides that if the total amount payable under item 3AB of Schedule 9 to the TG Regulations for applications to which subparagraph 43AAC(2)(b)(iii) of the TG Regulations (low value turnover application requirements) applies reaches $13,000 in a financial year, the applicant is not required to pay any further amounts for applications under subparagraph 43AAC(2)(b)(iii) in the financial year.

Item [2] substitutes the current heading of regulation 45A with a clearer, more relevant heading.

Item [3] – Further amendments
Item [3] increases most fees in regulation 45 and Part 2 of Schedule 9 to the TG Regulations by 2.4 per cent, subject to the TGA's rounding policy. This increase affects fees relating to a range of matters, including application fees for registration or listing on the Australian Register of Therapeutic Goods, application fees for manufacturing licences, evaluation fees, clinical trial notification fees, application fees for export certificates and inspection fees for manufacturing premises.

This item also increases the amount specified in paragraph 43AAJ(1)(b) of the TG Regulations by 2.4 per cent to $78,600 subject to the TGA's rounding policy. This item increases various fees specified in subregulations 45(4A), 45(9) and 45(11) of the TG Regulations by approximately 2.4 per cent subject to the TGA's rounding policy.

ATTACHMENT B

DETAILS OF THE *THERAPEUTIC GOODS (MEDICAL DEVICES) AMENDMENT REGULATIONS 2010 (No. 2)*

Regulation 1 – Name of Regulations
This regulation provides for the Regulations to be referred to as the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 2)*.

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

Regulation 3 – Amendment of *Therapeutic Goods (Medical Devices) Regulations 2002*
This regulation provides for Schedule 1 to amend the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Schedule 1 –Amendments

Item [1] – Amendment of fees
This item increases the fee for an abridged conformity assessment of a medical device, set out in paragraph 9.4(2)(b) of the *Therapeutic Goods (Medical Devices) Regulations 2002*, by 2.4 per cent.

This item also increases the fees for all relevant items in Part 1 of Schedule 5 to the *Therapeutic Goods (Medical Devices) Regulations 2002* by 2.4 per cent.

This item also increases the hourly fee of $320 specified in paragraph 2.1 (b) of Part 2 of Schedule 5 to the *Therapeutic Goods (Medical Devices) Regulations* 2002, for preparation by an assessor for a conformity assessment or a review of a conformity assessment certificate outside Australia, by 2.4 per cent, to $330.