

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument 2007 No. 163**

Subject: *Therapeutic Goods Act 1989*

*Therapeutic Goods (Medical Devices) Amendment Regulations 2007 (No. 1)*

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.

Paragraph 63(2)(h) of the Act provides that the regulations may prescribe fees in respect of matters under the Act or the regulations. Schedule 5 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) sets out the table of fees payable under the Act in relation to medical devices.

Paragraph 63(3)(b) of the Act provides, in part, for the reduction of fees in cases identified in the regulations.

The purpose of the Regulations is to increase, by 4.0 per cent, certain fees payable in relation to the regulation of medical devices, and to vary certain specified fees.

The Regulations:

- increase most of the fees prescribed in Part 1 of Schedule 5 to the Principal Regulations by 4.0 per cent; and
- align similar or like fees which have little or no effect on cost recoveries for consistency between the medicines and therapeutic devices fee schedules. Clinical trial notification (CTN) fees are reduced from \$270 to \$250.

The 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.

The changes to the Principal Regulations, when taken together with the changes to the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Charges) Regulations 1990* (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.

An overview of the Regulations is at [Attachment A](#), and details of those Regulations 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 (MEDICAL DEVICES) AMENDMENT REGULATIONS 2007 (No. 1)***

The purpose of the Regulations is to increase, by 4.0 per cent, most fees payable in relation to the regulation of medical devices, and to vary specified fees.

The 4.0 per cent general increase applied to fees 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.

Paragraph 9.4(2)(a) of the *Therapeutic Goods (Medical Devices) Regulations 2002* allows the Secretary of the Department of Health and Ageing (the Secretary) to conduct an abridged conformity assessment of a medical device in prescribed circumstances and to charge a reduced fee for that assessment. The Regulations increase the level of that applicable fee by 4.0 per cent.

Schedule 5 to the *Therapeutic Goods (Medical Devices) Regulations 2002* provides the list of fees chargeable under Chapter 4 (Medical Devices) of the Act. The fees payable pursuant to Schedule 5 include the processing of applications for inclusion of medical devices in the Australian Register of Therapeutic Goods (the Register) and initial and subsequent assessments under conformity assessment procedures. These fees reflect the costs incurred by the TGA in performing the various tasks under the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002*. The Regulations increase the level of most of the fees in Part 1 of Schedule 5 (General) by 4.0 per cent. The applicable fee in paragraph 2.1(a) of Part 2 (Additional Fees) of Schedule 5 remains the same, but the fee at paragraph 2.1(b) of Part 2 of Schedule 5 increases by 4.0 percent.

The new fees 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).

The TGA consulted with industry associations, including the Medical Industry Association of Australia, the Australian Dental Industry Association and AusBiotech on the increases to fees. The consultations, convened between 13 and 23 February 2007, consisted 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 fees. The outcome of the consultations was that industry was generally supportive of the TGA proposals for 2007-08 fees.

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).

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

**DETAILS OF THE THERAPEUTIC GOODS (MEDICAL DEVICES) AMENDMENT REGULATIONS 2007 (No. 1)**

Regulation 1 provides for the Regulations to be referred to as the *Therapeutic Goods (Medical Devices) 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 (Medical Devices) Regulations 2002*.

**Schedule 1 – Amendments****Item [1]**

This item increases the applicable fee for an abridged conformity assessment, in paragraph 9.4(2)(b) of the Principal Regulations, by 4.0 per cent. This 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 [2]**

This item increases most fees in Part 1 of Schedule 5 to the Principal Regulations by 4.0 per cent.

This item also adjusts the fee for notification of intention to sponsor a clinical trial of a medical device to be used solely for experimental use in humans applicable in item 1.8 of Part 1 of Schedule 5 of the Principal Regulations to from \$270 to \$250.

The general increases and the adjustment (*to item 1.8*) 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 [3]**

Paragraph 2.1(b) of Part 2 of Schedule 5 of the Principal Regulations provides the fee for an assessment that is required to be conducted outside of Australia – an amount calculated at the rate of \$290 (the current fee) for each hour of preparation by each assessor involved.

This item increases the rate for each hour of preparation by each assessor involved applicable in paragraph 2.1(b) of Part 2 of Schedule 5 to the Principal Regulations by 4.0 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.