

Therapeutic Goods (Medical Devices) Amendment Regulations 2004 (No. 1) 2004 No. 128

EXPLANATORY STATEMENT

STATUTORY RULES 2004 No. 128

Issued by the Authority of the Parliamentary Secretary to the Minister for Health and Ageing

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Amendment Regulations 2004 (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, 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.

Paragraph 63(3)(b) of the Act also allows for the reduction of fees in cases identified in the regulations.

The purpose of the Regulations is to increase, by 3.05 per cent, the fees payable in relation to medical devices. The increase will enable the TGA to continue to meet the Government's requirement that the TGA operates on a full cost-recovery basis.

Subregulation 9.4(2) of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) allows the Secretary of the Department of Health and Ageing 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 such reduced fees by 3.05 per cent.

Schedule 5 of the Principal Regulations 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 (ARTG) and initial and subsequent assessments under the conformity assessment procedures. These fees reflect the cost incurred by the TGA in performing the various tasks under the Act and the Principal Regulations. The Regulations increase the fees for all items specified in Schedule 5 by 3.05 per cent.

The 3.05 per cent increase in fees is made up of:

50 per cent of the annual Wage Cost Index (WCI) for the year ended December 2003	1.85 per cent
and	
50 per cent of the Consumer Price Index (CPI) for the year ended December 2003	1.20 per cent

The indexation formula based on the CPI and WCI has been used by the TGA since the 1998-1999 financial year, when the TGA was first required to operate on a full cost recovery basis. Industry has agreed that this formula is appropriate as a basis for fee increases in relation to therapeutic goods. The formula for the fee increases for the financial year commencing 1 July 2004 was discussed with the key industry body, the Medical Industry Association of Australia. This industry association has agreed to the formula as the basis for the 3.05 per cent increase to the fees payable under the Principal Regulations.

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

Details of the Regulations are set out in the [Attachment](#).

The Regulations commence on 1 July 2004.

ATTACHMENT

DETAILS OF THE *THERAPEUTIC GOODS (MEDICAL DEVICES) AMENDMENT REGULATIONS 2004 (NO. 1)*

Regulation 1 names the Regulations as the *Therapeutic Goods (Medical Devices) Amendment Regulations 2004 (No. 1)*.

Regulation 2 provides that the Regulations commence on 1 July 2004.

Regulation 3 provides that the Regulations amend the *Therapeutic Goods (Medical Devices) Regulations 2002* as provided in Schedule I.

SCHEDULE 1 - Amendments

Item 1 increases the level of reduced fees that apply for an abridged conformity assessment under regulation 9.4 by 3.05 per cent.

Items 2 and 3 increases the fees in all specified items of Schedule 5 by 3.05 per cent.