

# Therapeutic Goods Amendment Regulations 2004 (No. 3) 2004 No. 159

## EXPLANATORY STATEMENT

### STATUTORY RULES 2004 No. 159

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

*Therapeutic Goods Act 1989*

*Therapeutic Goods Amendment Regulations 2004 (No. 3)*

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. Part 2 of Schedule 9 of the *Therapeutic Goods Regulations 1990* (the Principal Regulations) sets out the table of fees payable under the Act.

Paragraph 63(3)(b) of the Act provides, in part, for the reduction of fees in cases identified in the regulations. Regulation 45 of the Principal Regulations provides that the Secretary of the Department of Health and Ageing may waive or reduce fees specified in Schedule 9, by, or to specified amounts and under certain circumstances.

The purpose of the Regulations is to generally increase fees payable under the Act by 3.05 per cent, introduce new fees, vary specified fees for certain purposes, and to make other minor technical amendments.

The Regulations:

- increase the fees prescribed in regulation 45 and Part 2 of Schedule 9 by 3.05 per cent, except as otherwise provided in these Regulations;
- decrease some fees in relation to prescription medicines;
- clarify the inspection fees payable for licences covering primary sites for the manufacture of blood and blood components;
- establish a separate fee structure for the inspection of premises for the production of human tissues;
- introduce fees related to the approval of advertisements intended for publication in certain media as a result of transfer of certain approval functions from the *Broadcasting Services Act 1992*;
- introduce two new fee items to cover circumstances where an evaluation of a prescription medicine requires the concomitant evaluation of either a medical or a therapeutic device;

- increase the threshold for the annual turnover of a business to \$65 000 before reduction of annual charges may apply for maintaining a manufacturing license by a business; and
- make other technical amendments.

The increase in fees in regulation 45 and Part 2 of Schedule 9 enables the TGA to continue to meet the Government's requirement that the TGA operate on a full cost-recovery basis.

The 3.05 per cent increase in fees is comprised of:

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

The level of fees was reviewed in consultation with industry associations, including Medicines Australia, the Generic Medicines Industry Australia, the Australian Self-Medication Industry, the Complementary Healthcare Council of Australia and the Medical Industry Association of Australia. The industry associations agreed to the WCI/CPI formula as the basis for the 3.05 per cent increase to the fees payable under the Principal Regulations.

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 commence on 1 July 2004.

## **ATTACHMENT**

### **DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2004 (NO. 3)***

Regulation 1 names the Regulations as the *Therapeutic Goods Amendment Regulations 2004 (No. 3)*.

Regulation 2 provides for the Regulations to commence on 1 July 2004.

Regulation 3 provides for Schedule 1 to amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations).

#### **Schedule 1 - Amendments**

##### **Item 1**

Regulation 42ZCAB of the Principal Regulations provides a written complaint mechanism in circumstances where an advertisement is alleged to contravene specified provisions of the Act, the Regulations or the Therapeutic Goods Advertising Code. This item amends subparagraph 42ZCAB(1)(a)(i) of the Principal Regulations by omitting reference to section 42D of the Act, which was repealed by the *Therapeutic Goods Amendment Act (No. 1) 2003*. This item also inserts additional references to sections 42DL, 42DM and 42DP of the Act, which are offence provisions relating to breaches of advertising requirements.

##### **Item 2**

This item increases the discounted evaluation fees payable by a sponsor when an application is lodged to register a therapeutic device in certain circumstances, or to vary information in the register about a therapeutic device. The different discounted fees reflect the kinds of evaluation that could be undertaken in relation to an application to register therapeutic devices or vary information contained in the Register about those devices. The proposal represents an approximate 3.05% increase to the current discounted fees.

##### **Item 3**

This item inserts a new heading to reflect the changes made to regulation 45A by item 4.

##### **Item 4**

This item increases the threshold for the amount of wholesale turnover of therapeutic goods required to establish eligibility for a reduction of the annual charge payable by a person who is required to hold a licence under Part 3-3 of the *Therapeutic Goods Act 1989* (the Act). The threshold would rise from \$62,985 to \$65,000. As the threshold relates to income, the increase is also based on the WCI/CPI formula agreed with industry.

##### **Item 5**

This item inserts a definition for "broadcast media" for the purposes of the Principal Regulations. This definition is the same as that contained in section 42B of the Act, and means, in relation to an advertisement or generic information, any means by which the information is disseminated electronically in a visible or audible form or a combination of such forms, other than a means declared in the regulations to be an exempt means.

##### **Item 6**

This item defines, for the purposes of the regulations, "primary site" as the principal manufacturing premises in the capital city of each State and Territory where human blood and blood components are manufactured; "regional area" as an area in a State or Territory other than the metropolitan area of the capital city of that State or Territory; "regional station" as a radio or television station that delivers radio or television programs to persons in a regional area only; and give "specified media" the meaning given by section 42B of the Act. The first definition are used in items 10, 11 and 12, while the other definitions are needed in item 15.

### **Items 7 and 8**

These items apply the existing definition of "submission" (Part 1 of Schedule 9) to applications for varying and entry of a prescription medicine in the Register under paragraph (a) of item 2A and the application fee for the evaluation of particular information submitted in relation to a prescription medicine under Item 2B in Part 2 of Schedule 9 to the Regulations. The effect of these amendments is that where several applications for variation of entries of therapeutic goods in the Register or registration of prescription medicines are lodged at the same time by a sponsor, and the goods concerned contain the same active ingredient, only one appropriate fee will apply.

### **Item 9**

This item inserts two new fees for the evaluation of prescription medicines where these are incorporated as an ancillary component of a therapeutic device or a medical device, and the data to be evaluated involves chemistry and toxicological data, and does not include any clinical data. The new fees apply where there is either an evaluation of the new chemical entity, or where there is either an extension of indications, a major variation in respect of the medicine incorporated as an ancillary component of a therapeutic or medical device or an evaluation is undertaken of various documentation in relation to that medicine. The fee is discounted as a corresponding evaluation or assessment is also required in relation to the therapeutic device or the medical device.

### **Item 10**

This item amends the inspection fees payable for inspecting manufacturing premises to exclude fees payable for inspections of manufacturing premises or operations for the preparation of human tissues. This is because a different fee is to apply for such inspections, as provided for by new Item 9ACA of Schedule 9 of the Regulations, inserted by item 13.

### **Items 11 and 12**

These items replace the phrase "metropolitan site" with "primary site" in items 9AB and 9AC of Part 2 of Schedule 9 to the Principal Regulations. The Principal Regulations have a two-tier licence structure for fees in relation to the inspection of manufacturing premises or operations for the preparation of blood and blood components. The higher fee is intended to be imposed to reflect the nature and scale of inspection required for a principal site where blood product manufacture occurs. The change clarifies the intention of the Principal Regulations and excludes the imposition of the higher fee on other sites that are coincidentally situated in a metropolitan area.

### **Item 13**

This item inserts a new fee item for inspections of manufacturing premises or operations related to licences for the preparation of human tissues. Regulation 9ACA imposes a fee structure whereby the inspections may be calculated according to the number of inspectors engaged per hour, or part of an hour.

### **Item 14**

This item increases the fee for the calculation of an application for certification under paragraph 58(3)(a) of the Act by approximately 3.05 per cent.

### **Item 15**

This item substitutes provisions for the approval of advertisements such that fees for approval of an advertisement intended to be published or broadcast in specified media (other than broadcast media) are distinguished from those prescribed for broadcast media. The approval of advertisements intended for the broadcast media has only recently been included in the Principal Regulations. "Regional station", "specified media" and "broadcast media" are defined in item 6.

### **Item 16**

This item increases the fees in Part 2 of Schedule 9 to the Principal Regulations by approximately 3.05 percent, except those fees provided for by other items in the Regulations.