

Therapeutic Goods Advertising Code: Amendments

EXPLANATORY STATEMENT

Issued by the Authority of the Delegate of the Minister for Health and Ageing

Therapeutic Goods Act 1989

Therapeutic Goods Advertising Code: Amendments

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a 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.

The Act includes provisions relating to advertisements for therapeutic goods. Subsection 3(1) of the Act defines the Therapeutic Goods Advertising Code (TGAC) as the Code known by that name and “notified in the Gazette with effect from the date of commencement of Schedule 1 to the *Therapeutic Goods Amendment Act (No.1) 2003* together with any amendments of the Code published by the Minister in the Gazette from time to time”.

The TGAC is now subject to the *Legislative Instruments Act 2003* which was implemented on 1 January 2005, negating the need for the Minister to publish amendments in the Gazette, but requiring the TGAC and all subsequent amendments to be included in the Federal Register of Legislative Instruments.

The Minister’s delegate in the TGA approved a number of amendments to the TGAC on 20 January 2005 which became necessary to ensure consistency between the Code and the requirements specified in Schedule 1 to the *Therapeutic Goods Amendment Act (No.1) 2003*.

The amendments commence on 20 January 2005.

DETAILS OF AMENDMENTS TO THE THERAPEUTIC GOODS ADVERTISING CODE.

Clause 2.3 is amended to ensure the TGAC definition of “specified media” is the same as that contained in the Act.

Clause 2.5 is a new clause which adds to the TGAC, the new definition of “broadcast media”, as contained in the Act. The subsequent clauses have been appropriately re-numbered.

Clause 2.6 and **Appendix 2** are amended to reflect the legislative amendment which moved the definition of “healthcare professional” from the Therapeutic Goods Regulations to the Act.

Appendix 3 is amended to update the contact details for the Advertising Services Managers who are appointed to pre-approve advertisements under the Regulations (prior to broadcast or publication) as Delegates of the Secretary to the Department of Health and Ageing.

Appendix 4 is amended to delete reference to the *Broadcasting Services Act 1992*, the legislation which previously established the advertising pre-approval scheme for broadcast media advertisements.