

EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ADVERTISING CODE 2007

Subsection 3(1), Therapeutic Goods Act 1989

BACKGROUND

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods for use in humans. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

The Act includes provisions relating to advertisements for therapeutic goods, including a number of provisions that require advertisements for therapeutic goods to comply with the Therapeutic Goods Advertising Code.

Subsection 3(1) of the Act defines the Therapeutic Goods Advertising Code (the Code) 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 Code is now subject to the *Legislative Instruments Act 2003*, requiring it and all subsequent amendments to be included in the Federal Register of Legislative Instruments (FRLI).

The Assistant Minister for Health and Ageing has approved a number of amendments to the Code, which are incorporated into the Therapeutic Goods Advertising Code 2007. The Therapeutic Goods Advertising Code 2007 replaces the previous Code, known as the Therapeutic Goods Advertising Code 2006 (‘the previous Code’).

The Code commenced on the day after it was registered in FRLI.

DETAILS OF AMENDMENTS TO THE CODE

The Code includes the following amendments which have been approved by the Assistant Minister for Health and Ageing.

Section 2 is amended by correcting minor typographical errors to the definitions of “advertisement” and “sponsor”.

Paragraphs 3(1)(c) and 3(3) are amended to make reference to the *Price Information Code of Practice*. This Code will be legally ‘underpinned’ in the Australia New Zealand Therapeutic Products Authority legislation.

A major, underlying principle of this Code is that advertisements containing price information about therapeutic goods (including Schedule 3 and 4 medicines) will not be deemed to be “advertisements” for “therapeutic goods” (within the statutory meanings of these terms), provided that such ‘price information advertisements’ comply with the provision of that Code. The amendments to Section 3 of the TGAC 2007 will assist with clarifying this position and implementing the PICP.

Paragraph 4(6) is amended to revert to the provision which was in place prior to August 2005 to prohibit advertisements for therapeutic goods from containing endorsements by healthcare professionals.

The Code) was amended in August 2005 to permit, for the first time, ‘healthcare professionals’ (including doctors), to endorse therapeutic goods in advertisements directed to consumers.

Concern has since been raised in the media and by peak healthcare professional organisations as to the appropriateness of such advertising. These organisations generally advise against endorsement of therapeutic goods by healthcare professionals in advertising to the public. The view that such endorsements are unethical has also been communicated.

The Therapeutic Goods Advertising Code Council (TGACC) agreed with these views and also expressed its concern that consumers could be misled as to the relevant efficacy of products and, as a result, may not choose the most suitable product for a particular circumstance.

In reverting to the “pre-August 2005” provisions, the following minor wording changes have been made to the new provision to:

- explain that the prohibition on individual healthcare professionals from endorsing therapeutic goods includes groups of healthcare professionals;
- clarify wording that associations who represent healthcare professionals that are permitted to make such endorsements, subject to conditions, must be “recognised peak professional associations” (eg. Pharmacy Guild of Australia); and
- strengthen the provision so as to clarify that well known healthcare professionals with a significant public profile, or any other healthcare professional, cannot continue to endorse therapeutic goods simply by dropping their professional title from the advertisements and instead, being referred to as “Mr” or “Ms”.

This amendment will retain the current provision which permits sponsorship of government agencies (but not “endorsement”). This provision was also first introduced to the Code in August 2005.

CONSULTATION

These amendments to the Code, based on a best-practice approach, have been considered and recommended to the Assistant Minister by the Therapeutic Goods Advertising Code Council (TGACC). The TGACC is established in the Therapeutic Goods Regulations to consider the requirements for the advertising of therapeutic goods and changes to the Code, and to advise the Minister accordingly.

The TGACC is broadly representative of all major stakeholder groups, including the therapeutic goods and advertising industries, media, consumers, healthcare professionals and government. Via their membership of the TGACC, all these stakeholder organisations have been consulted and directly involved with the development of the above amendments to the Code.