EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ADVERTISING CODE 2005

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 Parliamentary Secretary has approved a number of amendments to the Code, which are incorporated into the Therapeutic Goods Advertising Code 2005. The opportunity was also taken to renumber the sections of the Code to align it more closely to the standards required for FRLI. The Therapeutic Goods Advertising Code 2005 replaces the previous Code which was made on 16 July 2003 (and subsequently amended by the Therapeutic Goods Advertising Code: Amendments (20/01/05)) ('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 Parliamentary Secretary to the Minister for Health and Ageing.

Subsection 4(6) (formerly Clause 4.4 in the previous Code) is amended to change the requirements surrounding government agency and health professional endorsements in advertisements for therapeutic goods. While the prohibition on government agency endorsement will remain, the amendment permits sponsors to include reference in advertisements to any sponsorship arrangements they may have with government agencies. The proposed amendment will, for the first time, also permit individual healthcare professionals to endorse therapeutic goods in advertisements, providing the nature and basis of the endorsements are clearly disclosed in advertisements.

Subsection 4(7) (formerly Clause 4.5 in the previous Code) is amended to change the requirements relating to the use of testimonials in advertisements. The amendment requires that testimonials may now only show 'typical', rather than 'exceptional' cases.

Section 6 (formerly Clause 6 in the previous Code) is amended to require that the (already) mandatory display of approval numbers in print media advertisements, is now carried out by advertisers following a uniform approach.

Paragraph 7(1)(c) (formerly Clause 7.1.2 in the previous Code) is amended to clarify that the mandatory warning statements specified in the TGAC for analgesic products do not need to also appear on the product labelling, since label warning statements are already prescribed by the "Standard for the Uniform Scheduling of Drugs and Poisons".

Subsection 7(3) (formerly Clause 7.3 in the previous Code) is amended to complement the amendment to Subsection 4(7), and changes the requirements for the advertising of weight loss products. The amendment aims to ensure that advertisements, as well as promoting the advertised product, also include an appropriate balance between healthy eating and exercise in order to achieve safe and sustainable weight loss.

CONSULTATION

These amendments to the Code, based on a best-practice approach, have been considered and recommended to the Parliamentary Secretary 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.