EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ADVERTISING CODE 2006

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 2006. The Therapeutic Goods Advertising Code 2006 replaces the previous Code, known as the Therapeutic Goods Advertising Code 2005 ('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.

Section 2 is amended to add the following new definitions to the Code –

Therapeutic Goods Advertising Code Council (TGACC) means the broadly representative body of peak stakeholder groups, established in the Regulations to the *Therapeutic Goods Act 1989* to:

(a) consider the requirements for the advertising of therapeutic goods and changes to this Code, to accept submissions for this purpose and to advise the Minister accordingly; and

(b) to make recommendations to the Minister for achieving greater uniformity in approval processes and standards for the advertising of therapeutic goods,

amongst other matters (as outlined in the Regulations)"; and

typical means that which reflects the characteristic of a group ie. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

The definition of TGACC is in line with the establishment of this Committee and its terms of reference in the Therapeutic Goods Regulations and inclusion of a definition of "typical" in the TGAC 2006 is identical to that included in the draft Australia New Zealand Therapeutic Products Authority (ANZTPA) Therapeutic Products Advertising Code (TPAC).

Reference to 'typical' already appears at subsection 4(7) of the TGAC, which states, "Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only".

The previous (August 2005) amendments to this subsection of the TGAC have effectively prevented the further use of 'exceptional case' testimonials in advertisements. Some sponsors and advertisers have subsequently sought guidance as to the approach which is to be adopted when determining whether a testimonial is illustrating a "typical" case.

Paragraph 4(2)(c) is amended in a manner which now also prevents advertisements from being "likely to mislead", directly or by implication or through emphasis, comparisons, contrasts or omissions.

Paragraph 4(2)(f) is amended in a manner which now also prevents advertisements from being "likely to encourage" inappropriate or excessive use of therapeutic goods. Additionally, this paragraph is also amended to replace the word, "consumption" with the word, "use".

These two amendments strengthen the existing provisions in relation to misleading advertisements and advertisements which encourage inappropriate or excessive use of therapeutic goods, and are therefore in the public interest. Further, since the term, "consumption" could, in consumers' minds infer 'by ingestion only', the term, "use" is considered to be more appropriate.

Paragraph 6(3)(c)(i) is amended to add further, warning disclosure requirements in relation to direct marketing and Internet advertisements for therapeutic goods. This amendment addresses previous complaints from consumers that label warning statements about allergies, pregnancy, etc are not included in mail order catalogues and therefore, the consumers only became aware of these issues upon reading the product labels after the goods had been ordered and paid for.

The complainants raised concern that since they had no access to the product packaging / labelling prior to making the decision to purchase, they needed to rely entirely upon the catalogue advertisement. This has lead to the purchasing of products they have subsequently been unable to use. These additional warning disclosure requirements are already included the draft ANZTPA TPAC.

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.