



Information for Sponsors

Advertising Complementary Medicine Products to Healthcare Professionals

The Complementary Healthcare Council (CHC) has been working with the Therapeutic Goods Administration (TGA) about concerns raised over **the seriously inappropriate advertising of complementary medicines to various healthcare professionals**. This was due to some 'practitioner-only manuals' being found to unlawfully promote LISTED medicines (AUST L) for the treatment of serious and life threatening medical conditions, which is in breach of various requirements of the *Therapeutic Goods Act 1989* ("the Act").

In response to this situation, the CHC Practitioner Medicine Technical Committee (PMTTC) was formed. The PMTTC held their first meeting in May 2010 to discuss issues raised on the matter at the CHC March 2010 Forum where a closed workshop was held. The main outcome from the meeting was to establish a proposed timeline to ensure industry compliance to the TGA advertising provisions for advertising directly to healthcare practitioners.

As part of negotiations between the CHC and the TGA Advertising and Recalls Section, the CHC can confirm the following timeline for industry compliance with the legislative requirements:

Proposed Process for Compliance – Advertising to Practitioners

Stage of Compliance:	Expected Due Date:
Guidance provided to industry on appropriate content of practitioner only product manuals (TGA approval required)	currently in progress
Industry workshop proposed (held by the CHC) to educate industry on the newly developed guidance	January/February 2011
Industry review of ARTG entries for practitioner only products to ensure compliance	April 2011
Industry review of practitioner only product manuals to ensure compliance with ARTG entries	July 2011
Redesign practitioner only product manuals based on amendments	January 2012
CHC to meet with Recalls and Advertising Section to ensure timeline is progressing as expected	February 2012
Print and release revised practitioner only product manuals (if required)	February 2012
CHC to write a letter to industry advising to destroy old, non compliant manuals/guides deemed to be advertising	End February 2012
Amnesty period ceases TGA - Section 8 Notices	31 March 2012

The TGA have advised that after **31 March 2012**, formal regulatory action will be sought, including the possible cancellation of products from the Australian Register of Therapeutic Goods (ARTG), against those who continue to inappropriately advertise and distribute non-compliant advertising material to healthcare professionals.

Members should note that the TGA, if warranted, may take regulatory action for major legislative breaches, irrespective of the proposed timeline.

Any advertising material (such as ‘practitioner only manuals’), which are non-compliant, should be removed from circulation and not be re-distributed until amended to ensure future and on-going compliance with the relevant advertising provisions of the legislation (refer below for relevant sections of the Act).

Definition of an Advertisement

An **advertisement** in relation to therapeutic goods as defined in the Act includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

Advertisements can be in the form of **broadcast media** (where the advertisement is disseminated electronically in a visible or audible form or a combination of the two), **mainstream media** (any magazine or newspaper for consumers) or **non-specified media** (brochures, leaflets, flyers, shelf talkers, newsletters, point of sale material, videos, audio tapes and catalogues, as well as any magazines or journals that are not mainstream media).

‘Practitioner-only manuals’ fall within the statutory meaning of an “advertisement” where they ‘... promote the use or supply of the goods’.

Definition of a Healthcare Professional

A **healthcare professional**, as defined by the *Therapeutic Goods Act 1989* includes:

- (a) medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths; or
- (b) persons who are:
 - (i) engaged in the business of wholesaling therapeutic goods; or
 - (ii) purchasing officers in hospitals; or
- (c) herbalists, homoeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists registered under a law of a State or Territory.

Advertisements directed exclusively to healthcare professionals are not required to comply with the *Therapeutic Goods Advertising Code* provisions however they must comply with other relevant requirements within the Act.

Specifically, the offence provision at Section 22 (5) states that, ‘a person commits an offence if:

- (a) the person, by any means, advertises therapeutic goods for an indication; and
- (b) the therapeutic goods are included in the Register; and
- (c) the indication is not an indication accepted in relation to that inclusion.

Further, under Section 28, it is a Condition of Listing in the Australian Register of Therapeutic Goods that *“the person in relation to whom the subject goods are registered or listed will not, by any means, advertise the subject goods for an indication other than those accepted in relation to the inclusion of the goods in the Register.”*

A breach of a Condition of Listing constitutes grounds for the TGA to **CANCEL** the listing of a medicine from the ARTG; an action which would mean that it would be illegal to supply the product on the Australian market.

For more information regarding the PMTC proposed timeline of compliance, please contact Emma Burchell at technical@chc.org.au or by telephone 02 6260 4022

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