Complementary Healthcare Council of Australia



# Member Alert

## Restricted representations included in coded indications and their inclusion in advertising claims

Dear CHC Member,

There appears to be widespread and ongoing confusion amongst industry as to which specific coded indications are considered by the Therapeutic Goods Administration (TGA) to be restricted representations requiring gazettal prior to being advertised to consumers.

Indeed for many years the general understanding amongst industry was that because the Complementary Medicines Evaluation Committee (CMEC), now the Advisory Committee on Complementary Medicines (ACCM), considered the suitability of coded indications for listed medicines, that if CMEC did not recommend a coded indication as a restricted representation and there were no limitations to adding such coded indications to the Australian Register of Therapeutic Goods (ARTG), sponsors had no reason to suspect that they may require an advertising exemption prior to advertising to consumers.

However, in 2011 the Complaints Resolution Panel (CRP) put to the Therapeutic Goods Advertising Code Council (TGACC) the issue about the potential lack of legislative underpinning for the use of some coded indications in advertising. At this time, the TGACC requested the TGA resolve the matter with speed and efficiency. The TGA's permitted indications project has been in consultation with industry since then, and it is said that the conclusion of this project will clarify the uncertainty once it has been finalised and implemented. Until such time the situation remains unclear. Please note that the CHC's Regulatory Technical Committee is liaising with the TGA to refine the list of permitted indications for use in listed medicines.

**Current situation**

The CHC was recently made aware of the TGA clarifying its position on the use of the term 'arthritis' in advertising after receiving a copy of correspondence directed to one of our members. We instigated a meeting with the TGA, and teaming up with ASMI, met with the Head of Office of Product Review, Ms Jane Cook; Head of Office of Complementary Medicines, Ms Trisha Garrett; Principal Legal Adviser, Ms Philippa Horner and Advertising unit representatives to address the issue of coded indications that contain restricted representations and their inclusion in advertising claims. Jointly, the associations urged the TGA to publicise their position to all of industry, and to explain clearly which other potential restricted representations would require gazettal prior to being advertised to consumers.

Moreover, we are extremely concerned that such a blanket decision by the regulator ahead of the coded indications and labelling reforms being finalised, will have an enormous knock on effect on product labels, websites and packaging. This clearly goes against the Government's approach to the reduction of regulatory red tape, especially in the absence of any evidence being provided to indicate public health risks or concerns.

**A way forward**

The CHC maintains that this issue be addressed as part of the permitted indications project and labelling reforms, however in the meantime advertising of these indications needs to be clarified. We are currently

looking into the possibility of a group application for approval to use the restricted representation 'arthritis' in advertising within the common range of listed complementary medicine products.

We have urged the TGA to publish a clear statement as to their position with regard to restricted representations, together with the list of coded indications that they consider to include potential restricted representations requiring gazettal prior to being advertised to the public. We believe the publication of this information will go some way towards clarifying the issues for advertisers.

We remain concerned about the impact on advertisers who may currently be using such affected claims, as this may appear as though the legislation has suddenly changed without any consultation or forewarning. This is an issue that does need to be made clear from the regulator to the sponsor.

We continue to press the TGA for clarity on this issue as a matter of urgency, and are ready to escalate to the Health Minister if required.

**Background: Content of TGA Correspondence to Industry Member**

On the 13 March, 2014 the CHC received the following communication from the TGA indicating that: "The TGA shared the view of the CRP that the term 'arthritis' without qualification as to the severity or type is likely to breach Section 5(2) of the Therapeutic Goods Advertising Code (TGAC), as documented in determination of complaint No 2013-03-005.

Advertising provisions prohibit advertisements directed to the public from referring expressly or by implication to serious forms of disease, conditions, aliments or defects specified in Part 2, Table 1 of Appendix 6 of the TGAC. Further restricted representations are generally accepted to be:

- Not appropriate to be diagnosed and/or treated without consulting a suitably qualified health professional; and or
- Beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified health professional.

'Arthritis' is defined in Stedman's Medical Dictionary *as inflammation of a joint; state characterised by inflammation of the joints*. Part 2, Table 1 of Appendix 6 of the Advertising Code includes "diseases of joint, bone, collagen and rheumatic disease" for which advertising of serious forms are restricted. Unqualified reference to arthritis in advertising claims could, therefore, be taken by the reasonable consumer to be reference to serious forms of disease such as osteoarthritis or rheumatoid arthritis".

The Electronic Listing facility (ELF) provides a list of indications that sponsors may choose from when self-selecting their medicine on the Australian Register of Therapeutic Goods (ARTG) for early market access. In some instances, such an indication may refer to a restricted representation and in those cases, prior approval to use such a restricted representation in advertisements available to the public must be obtained under the *Therapeutic Goods Act 1989* (refer to Chapter 5, Part 5-1, Division 3 of the Act).

To clarify, the use of a coded indication provided in the list on ELF does not automatically grant the sponsor approval to use an indication that refers to a restricted representation on either the label (where it promotes the use or supply of the medicine) or in advertising available to the public.

Sponsors of listed medicines, who wish to use a restricted representation in advertising available to the public, including the label of the medicine, must make an application to the Secretary of the Department of Health under Section 42DE of the Act. In making a decision on the application, the Delegate to the

Secretary must take into consideration matters specified under Section 42DF of the Act, including any recommendation from the TGACC and any advice from TGA advisory committees.

An approval (or refusal) of a restricted representation must be in writing and currently approvals are routinely published on the TGA website. Please note that the TGA, through the proposed complementary medicines reforms, intends to simplify the arrangements for the lawful use of restricted representations in listed medicine advertising (including product labels) where such representations are made in the context of the medicine's indications and where supported by an appropriate level of evidence".

**Resources**

The TGA website includes the following information in relation to restricted representations and application for approval to use a restricted representation in advertising.