

Ref: 11.11.6 — 18 August 2010

The Project Officer
Advertising Consultation – Regulatory Reform
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir / Madam

RE: ADIA Response – Advertising therapeutic goods consultation paper

Thank you for the opportunity to comment on the consultation paper reviewing options for the reform of therapeutic goods advertising issued by the Therapeutic Goods Administration (TGA). The Australian Dental Industry Association (ADIA) is pleased to provide this response and, in so doing, takes the opportunity to raise issues associated with the matter but not directly addressed in the paper.

Context of this response

ADIA is the peak representative body for the manufacturers, importers and suppliers of dental products supplied to dentists and allied oral healthcare professionals. The Association has approximately two hundred and fifty members who supply in excess of ninety-five percent of the equipment and consumables used in dentistry.

The products supplied include equipment (including but not limited to dental chairs and associated furniture, sterilisation equipment and imaging equipment in addition to hand tools) and other items ranging from false teeth (in various forms), teeth restoration materials, and consumable items such as latex gloves in addition to various cloth and paper products. Some products supplied by the Australian dental industry, such as toothpaste and dental floss, are provided in considerable quantities as over-the-counter (OTC) items. The vast majority of the products supplied by the Australian dental industry appear on the Australian Register of Therapeutic Goods (ARTG), the supplier (the sponsor of the ARTG entry) albeit having been assessed as relatively low-risk items.

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Advertising and the dental industry

The Australian dental industry advertises its products to two different markets. With respect to over-the-counter goods such as toothpaste and dental floss, these are marketed directly by Sponsors but the bulk of advertising activity is generally undertaken by retailers to the general public (primarily as supermarket goods).

With respect to medical devices, the dental industry itself targets its advertising to dentists and allied oral healthcare professionals, thus these arrangements fall within the scope of the *Therapeutic Goods Advertising Code* made under the *Therapeutic Goods Act (Clth) 1989*.

Separating advertising from promotion

ADIA appreciates the difference between advertising of therapeutic goods and promotion of the same, and is also contributing to the Australian Government's review of the framework for the promotion of therapeutic goods. ADIA, as a participant in the cross-industry panel convened to look at industry self-regulation of therapeutic goods promotion, will respond to issues associated with promotion via that means.

ADIA believes it necessary to redefine what constitutes an "advertisement" as the current definition in the *Therapeutic Goods Advertising Code* to be so narrow as to include many statements made by a Sponsor, including those correcting an error of fact on a social networking site. It is therefore desirable that the definition of the rule to more readily facilitate a corrective statement issued by a Sponsor in response to an error of fact published by a third party.

Knowledge of arrangements for advertising of therapeutic goods

Those ADIA members that are Sponsors have a strong awareness of the current arrangements for the advertising of therapeutic goods. As part of the Association's services to support member companies, it is anticipated that in the first half of 2011 a training program will be developed and delivered nationwide to increase overall industry awareness.

The role of electronic media and advertising

Advances in technology have altered the nature of advertising. Traditional vehicles such as advertisements in publications or direct mail are being supplemented, and increasingly replaced by, advertising on social media internet portals (*i.e.* FaceBook and Twitter) and also on blogs where this is not inconsistent with *Therapeutic Goods Advertising Code*. The challenge associated with such advertising platforms is that the advertising activity may not be an activity of the Sponsor, thus there are limitations on the Sponsor's ability to respond to, and where necessary correct, and false or misleading claims.

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Common regulatory framework

ADIA believes that there should be a common (*i.e.* applies equally to all forms of media and distribution) regulatory framework for advertising of therapeutic goods.

International harmonisation of regulatory frameworks

The increasing use of the internet by both healthcare professionals and the public as a resource to obtain information on therapeutic goods will, to a limited extent, render impotent an Australian regulatory framework. In this context, it would not be unhelpful, from a Sponsors' perspective, if any new Australian regulatory framework was consistent with that of other jurisdictions, primarily in North America, Europe and New Zealand.

Pre-approval process for advertisements

The current framework for approval of therapeutic goods advertisements are, in ADIA's view, sound and should be retained in most aspects. Where an advertisement is making a restricted representation the approval arrangements are sound, as is the current exemption for pre-approval in other cases.

Complaints processes and mechanisms

ADIA has been advised that the Complaints Resolution Panel (CRP) receives so few complaints relating to advertisements for (dental) therapeutic goods that it is not possible to make an assessment of the current arrangements and their effectiveness or otherwise in the Australian dental industry. Similarly, it has been some years since ADIA has received a complaint in this area. That said, as a matter of principle ADIA supports a self-regulation model where the relevant industry association has the authority to publish, and enforce compliance with, an industry-wide code of practice.

As referenced earlier, ADIA is a participant in a cross-industry panel convened to look at industry self-regulation of therapeutic goods promotion. Although the work of this panel is continuing, it is becoming apparent that there are issues common to therapeutic goods advertising and promotion. In this context one option may be to develop a single dispute resolution mechanism that covers the (presumably separate) industry codes relating to both advertising and promotion of therapeutic goods.

Given that many Sponsors have strong relationships with overseas companies, there is benefit in sharing and promotion of information between jurisdictions. It is possible that an advertisement found to be improper in one jurisdiction may also be used in another jurisdiction, thus this cross-sharing of information across jurisdictions would play a proactive role in allowing industry to take appropriate corrective measures without the intervention of the regulator.

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ADIA Code of practice

As part of a proactive approach to strengthening the integrity Australian dental industry, ADIA is shortly to embark upon a review of its Code of Practice. An activity that was scheduled to take place in any event, the importance of this is underpinned by the Australian Government expressing a clear interest in industry-self regulation of therapeutic goods. ADIA is awaiting the recommendations from the cross-industry panel convened to look at industry self-regulation of therapeutic goods promotion before embarking upon the review of its Code.

ADIA is yet to finalise the scope for reviewing its Code of Practice, however we are pleased to advise that it is envisaged that this review will include a considerable strengthening of arrangements associated with the advertising of therapeutic goods, thus strengthening industry self-regulation in this area.

Given the relatively small number of complaints received concerning advertising of (dental) therapeutic goods, there is a strong argument that there is not a major issue associated with the advertising of the same. This reflects the commitment of the Australian dental industry to comply with the regulatory framework, and the work of ADIA in this area.

It is acknowledged that ADIA's response does not address the full range of issues raised in the discussion paper, primarily only touching upon those relevant to the Australian dental industry. Naturally, ADIA is willing to work with the Australian Government as it further considers options for reforms in this area.

Please feel at liberty to contact ADIA to discuss this issue further.

Yours faithfully



Troy R Williams AFAIM MAICD
Executive Officer