



**AUSTRALIAN DENTAL
ASSOCIATION INC**
Incorporated in the ACT ARBN 131 755 989

14-16 Chandos Street St Leonards NSW 2065

All Correspondence to:
PO Box 520 St Leonards NSW 1590

27 August 2010

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

Dear Project Officer,

Re: Advertising Therapeutic Goods In Australia: Consultation Paper

The Australian Dental Association Inc. (ADA) writes to you today with reference to the Department of Health and Ageing, Therapeutic Goods Administration (TGA), Advertising Therapeutic Goods In Australia: Consultation Paper.

About the ADA

The ADA is the peak national professional body representing around 12,000 members. ADA members work in both the public and private sectors. The ADA represents the vast majority of dental care providers.

The primary objectives of the ADA are:

- to encourage the improvement of the oral and general health of the public and to advance and promote the ethics, art and science of dentistry; and
- to support members of the Association in enhancing their ability to provide safe, high quality professional oral healthcare.

Comments

The ADA is a professional association representing dentists and therefore has little to do with advertising of pharmaceutical products. Our members are, however, a target group for advertising. As such, the ADA's position is that it will support regulation that requires advertisers to provide a balanced and fair representation of products. Beneficial claims and propensities for products should be true and accurate. Such claims must be able to be substantiated by valid scientific evidence.

From the perspective of the ADA, the harmonisation of industry requirements with those for dentists and allied oral healthcare professionals is highly desirable. The ADA would like to bring two ADA policies to the attention of the TGA:

- Policy Statement 3.4: Sponsored Continuing Development Activities; and
- Policy Statement 4.14: Dentists' Relationships with the Pharmaceutical Industry.

These policy statements are attached for your information.

Policy Statement 3.4: Sponsored Continuing Development Activities

Often manufacturers and distributors of pharmaceutical products use the opportunity of providing continuing professional development (CPD) to advance claims for

products manufactured or distributed by them. It affords the supplier the opportunity to extol the virtues of a product under the guise of provision of CPD - that is in a context of learning. Claims made in such circumstances are often able to be 'presented' by credible persons and provide an element of scientific validation to claims made that may not otherwise be justified.

In the policy statement attached you will observe that the ADA insists that scientific and clinical CPD activities should be presented in an impartial manner so that the scientific basis of the activity is not distorted by commercial considerations.

The ADA recognises that sponsors are entitled to recognition and appreciation for their financial assistance and support in facilitating activities by expert presenters. However, if the venue is in relation to the provision of CPD appropriate disclosures it must be clearly provided to the participants. Unrealistic expectations for products or overstated claims by sponsors as to a professional's ability to use products or techniques must not be exaggerated. Such sponsorship should be clearly identified.

Policy Statement 4.14 Dentists' Relationships with the Pharmaceutical Industry

Professional interactions between dentists and the pharmaceutical industry should have as their main objective the advancement of the health of patients rather than the self-interests of dentists or the industry.

The primary way in which dentists should be informed about pharmaceutical products should be through independent CPD, which could be enhanced by the dental profession and the pharmaceutical industry cooperating in its delivery.

Transparency of arrangements between dentists and the pharmaceutical industry will improve confidence in the self-government role of the dental profession and ensure best treatment outcomes for patients. Further, the ADA believes dentists should not accept a fee or equivalent consideration from pharmaceutical manufacturers or distributors in exchange for participating in promotional or similar activities.

Any research projects requiring the active cooperation between the dental profession and the pharmaceutical industry should be conducted under strict ethical guidelines.

Pharmacists, when dispensing drugs, have a valuable role in checking the suitability of prescribed drugs.

It is also important that dental students are adequately trained in ethical issues surrounding the use of pharmaceutical products.

Conclusion

Thank you for your interest in this important area of concern.

I look forward to your response.

Yours sincerely



Dr Neil Hewson
Federal President



AUSTRALIAN DENTAL ASSOCIATION INC.

POLICY STATEMENT 3.4

SPONSORED CONTINUING PROFESSIONAL DEVELOPMENT ACTIVITIES

1 Introduction

- 1.1 The Australian Dental Association Inc [ADA] and its Branches have conducted independent Continuing Professional Development (CPD) activities for many years.
- 1.2 Recently, there has been increasing sponsorship of CPD activities by those who have a commercial interest in the topic, giving rise to concerns regarding the clinical and scientific independence of such presentations.
- 1.3 This Policy Statement also applies to CPD activities conducted by the ADA and its Branches.

2 Principles

- 2.1 Scientific and clinical CPD activities should be presented in an impartial manner such that the scientific basis of the activity is not distorted by commercial considerations.
- 2.2 Sponsors are entitled to recognition and appreciation for their financial assistance and support in facilitating activities by expert presenters.
- 2.3 Registrants have a right to know whether or not the activity they are participating in is sponsored and, if so, that it will not be restricted to products offered by the sponsor.

3 Policy

- 3.1 Scientific and clinical activities should refer to the range of products required to address particular conditions and treatments, and not only those products offered by the sponsor.
- 3.2 Registrants attending recognized CPD events should be advised by the presenter of any relationships with sponsors, preferably during introductory remarks.
- 3.3 The financial support offered by sponsors should be acknowledged formally during the introduction of presenters and when thanking presenters.
- 3.4 When companies simply wish to demonstrate products, they should set up an activity of their own. While not denying the educational value to the profession of such activities, especially in the case of new products, the ADA would not wish to imply its endorsement of the product by its "badging" of the activity.
- 3.5 Depending on the level of support, sponsors' logos could be included on promotional material for events and on introductory slides, but always separated from the ADA logo.
- 3.6 This Policy Statement should be made available to both sponsors and presenters during initial discussions about proposed events.

Policy Statement 3.4

Adopted by ADA Federal Council, April 20/21, 2006.

DENTISTS' RELATIONSHIPS WITH THE PHARMACEUTICAL INDUSTRY¹

1 Introduction

- 1.1 The use of products produced by the pharmaceutical industry form an important part of the practice of dentistry.
- 1.2 The pharmaceutical industry and dentists interact in the following areas where dentists:
- administer and prescribe drugs in the practice of dentistry;
 - recommend the use of other pharmaceutical products;
 - receive complimentary information and promotional products from the pharmaceutical industry; and
 - are involved in research and Continuing Professional Development (CPD) activities in conjunction with the pharmaceutical industry.
- 1.3 **Definition:**
- 1.3.1 PHARMACEUTICAL INDUSTRY is industry involved in the development, testing, manufacturing and marketing of drugs and other medicinal products.

2 Principles

- 2.1 Professional interactions between dentists and the pharmaceutical industry should have as their primary objective the advancement of the health of patients rather than the self-interests of either dentists or the industry.
- 2.2 The primary way in which dentists should be informed about pharmaceutical products should be through independent CPD which could be enhanced by the dental profession and the pharmaceutical industry cooperating in its delivery.
- 2.3 Transparency of arrangements between dentists and the pharmaceutical industry will improve confidence in the self-government role of the dental profession and ensure best treatment outcomes for patients.
- 2.4 Any research projects requiring the active cooperation between the dental profession and the pharmaceutical industry should be conducted under strict ethical guidelines.
- 2.5 Pharmacists, when dispensing drugs, have a valuable role in checking the suitability of prescribed drugs.
- 2.6 It is important that dental students are adequately trained in ethical issues surrounding the use of pharmaceutical products.

1. This Policy Statement is linked to other Policy Statements: 1.2.2 *Community Oral Health Promotion: Diet and Nutrition*, 1.4 *Research*, 3.4 *Sponsored Continuing Professional Development Activities*, 4.6 *Dental Industry* & 5.4 *Principles of Ethical Dental Practice*

3 Policy

3.1 When using or prescribing pharmaceutical products dentists should:

- only administer and prescribe drugs in the practice of dentistry;
- have the advancement of the health of patients as their primary objective;
- not dispense prescription drugs unless there is no reasonable alternative;
- not allow their prescribing habits or use of products to be influenced by personal gifts from the pharmaceutical industry or similar bodies; and
- always maintain professional autonomy, independence and commitment to the scientific method.

3.2 CPD and education regarding pharmaceutical products is essential for dentists to be well informed, and the pharmaceutical industry may contribute to such events provided:

- they address the educational needs of the targeted dental audience and not the marketing needs of the contributing pharmaceutical company;
- dentist organisers have the ultimate decision regarding the organisation, content and choice of CPD activities;
- CPD organisers and their delegates are not in a position of conflict of interest by virtue of any affiliation with the sponsors of those activities;
- financial and/or other aid received is acknowledged in the programme;
- the sponsor's product is not excessively promoted; and
- any travel and accommodation arrangements, social events and venues for industry sponsored CPD activities are in keeping with the arrangements which would be in place in the absence of industry sponsorship.

3.3 When dental research requires the active cooperation between the dental profession and the pharmaceutical industry:

- dentists and dental researchers should satisfy themselves that the project has genuine merit, is not detrimental to the development of other more appropriate areas of research and is ethically defensible, socially responsible and scientifically valid;
- the participation of dentists in research activities sponsored by the pharmaceutical industry should always be preceded by formal approval of the project by an appropriate review body, which should also receive a report upon its completion, and such review should follow national guidelines of the type promulgated by the National Health and Medical Research Council's Australian Health Ethics Committee and similar bodies; and
- all monies provided for research should be held in trust for the specified purposes, and such an account should be available for audit.

- 3.4 Dentists should not:
- be affiliated with pharmaceutical manufacturers if the nature of their affiliation influences their dental practice in an inappropriate fashion;
 - knowingly invest in pharmaceutical companies where the investment might influence inappropriately the manner of their practice or their prescribing behavior; nor
 - accept a fee or equivalent consideration from pharmaceutical manufacturers or distributors in exchange for participating in promotional or similar activities.
- 3.5 Dentists may accept educational materials from pharmaceutical companies appropriate to their areas of practice.
- 3.6 The curricula of Dental Schools should include formal training on the ethical association between dentists and the pharmaceutical industry.
- 3.7 The pharmaceutical industry should eliminate sugars and acids as additives in medications taken orally.

Policy Statement 4.14

Adopted by ADA Federal Council, April 16/17, 2009.

Amended by ADA Federal Council, November 12/13, 2009.