

Ref: 11.11.18U — 18 October 2017

Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir / Madam

RE: ADIA Comment – Therapeutic Goods Advertising Code Review

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA) takes this opportunity to tender advice concerning the Therapeutic Goods Administration's (TGA) consultation for improvements to the Therapeutic Goods Advertising Code (the 'Code').

The ADIA membership supplies more than ninety-five percent of the products used by dentists and allied oral health professionals nation-wide. ADIA's approach to policy advocacy places significant emphasis on ensuring that member businesses support activities to influence the commercial, technical and regulatory environment in which the dental industry operates. It is in this context that we can advise that the position set out below can be considered to represent that of the entire sector.

ADIA recognises that the TGA is reforming the therapeutic goods advertising scheme to facilitate the change from the existing pre-approval scheme to a self-regulatory scheme in accordance with the Government's acceptance of the majority of recommendations made by the Independent Review of Medicines and Medical Devices Regulation (MMDR).

ADIA Members are well positioned to operate lawfully within the proposed self-regulatory framework. Members adhere to the *ADIA Code of Practice* which outlines clear requirements for the advertisement of products directed exclusively to healthcare professionals and those with responsibility for the purchasing of medical devices. The *ADIA Code of Practice* also stresses that Members are also obligated to adhere to the *Code and the Competition and Consumer Act 2010 (Cth)* when advertising to consumers and where otherwise appropriate.

ADIA supports the reforms proposed in the TGA's consultation paper insofar as they relate to the dental industry. ADIA strongly supports the drafting of clear prescriptive rules that minimise subjectivity in the interpretation of provisions in the new Code. As the TGA moves towards a self-regulatory scheme, clarity of definitions and rules are necessary for the effective functioning of the advertising regime going forward.



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Likewise, the provision of supplementary guidelines and educational material will assist industry in conforming to the Code. However, the TGA must ensure that the Code itself is exclusively used for interpretation of conformity and that supplementary guidelines and educational material are not relied upon for the determination of conformity.

ADIA supports consistency in advertising requirements for medicines and medical devices where appropriate. It would however be helpful if the TGA were to provide further information with respect to the reasons for which it would consider mandating unique requirements for medical devices. Additional clarity in this regard would enable ADIA to provide more specific feedback to the TGA.

Further, both the existing and proposed scheme do not address the challenges associated with online advertising. Sponsors may wish to include on their websites information that is targeted to healthcare professionals. However, the nature of the internet is such that should a consumer come across this information, even if it is not targeted at or otherwise linked to them specifically, the Sponsor may be in unintentional contravention of the Code. Further consideration should be given to this issue to minimise unintended consequences. The TGA may wish to address this peculiarity within the scope of the Code or at a minimum provide clear guidance material for sponsors who may find themselves in this situation.

As the TGA continues its deliberations with respect to this matter, if there is a need to seek guidance on this matter please contact the ADIA Policy & Research Manager, [REDACTED] who can be reach via email at [REDACTED] or by telephone on 1300 943 094.

Yours faithfully

[REDACTED]
Troy R Williams FAIM MAICD
Chief Executive Officer