

Ref: 11.11.34F — 6 June 2018

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

Dear Sir / Madam

**RE: Complaints Handling – Advertising of Therapeutic Goods to the Public**

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) complaints handling process for the advertising of therapeutic goods to the public.

ADIA's member businesses supply 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 in its submission to the TGA's 2018 consultation on the draft *Therapeutic Goods Advertising Code 2018* and associated guidance material underscored its support for the long-overdue reforms, stemming from the Government's acceptance of Recommendations 55, 56, and 57 of the 2015 *Review of Medicines and Medical Devices Regulation*, designating the TGA as the centralised complaints management body for the advertising of therapeutic goods to the public.

In addition to outlining broad support for the TGA's reform proposals, ADIA highlighted improvements to the draft documentation to ensure that provisions contained therein, particularly as they relate to internet advertising, do not inadvertently impose onerous compliance requirements on industry. In this context, ADIA is pleased to tender the following advice with respect to the enforcement of the advertising regulatory regime:

**Complaints Handling Model**

The TGA's proposed complaints handling procedures would allow to the TGA to utilise an expanded suite of regulatory tools to enable it to make sufficiently flexible decisions with regards to compliance and enforcement. ADIA strongly supports the TGA's





proposal to adopt a risk-based approach to compliance actions, where regulatory activities are undertaken in a manner proportionate to the risk posed to the public. The proposed tiers of advertising breaches and the corresponding regulatory action appear to be reasonable.

As acknowledged in the TGA's consultation paper, the reasons for non-compliance are nuanced. The vast majority of businesses either voluntarily comply with advertising requirements or at the very least genuinely attempt to do so. In these cases, constructive notification and support through guidance to improve compliance systems is the best way to improve compliance. It appears that the TGA's approach to enforcement and compliance is reflective of this nuance.

ADIA's key recommendation in this area is that the TGA, when determining its response to an advertising breach, take into consideration whether or not the business is a Small and Medium Enterprise (SME). The Australian Government Treasury notes that "small businesses have fewer resources Small businesses have fewer resources – be it time, information, money or staff – at their disposal to cope with their regulation obligations".<sup>[1]</sup>

In this context, the Treasury has advised that regulators should ensure that "small business are considered differently to large business".<sup>[2]</sup> Therefore, it would be appropriate for the TGA to adopt a considered degree of fair consideration with respect to SMEs that, by their nature, face greater challenges in developing compliance systems. In this context, SMEs should be subject to a degree of leniency relative to larger businesses that, quite reasonable, carry with them greater expectations with respect to compliance systems and knowledge.

### **Reporting Outcomes and Measuring Performance**

ADIA supports the proposal to report bi-annually on key performance indicators (KPIs), in relation to targets for time required to action and close complaints. However, ADIA also advises that the TGA report on the number of instances where a complaint has not been included in these KPIs and a break-down of the reasons for exceptions being granted. This will improve the transparency of the TGA's reporting and will ensure that the exception parameters are not subject to unreasonable expansion over time.

### **Education and Guidance**

Having established that education and guidance are the most powerful regulatory tools available to the TGA to both ensure ongoing compliance and respond to low-level breaches, it is absolutely crucial that it prepare documentation to support this.

ADIA strongly supports the development of guidance documentation and its presentation in a range of formats including social media, stakeholder workshops, printed fact sheets, and e-learning programs. ADIA is pleased to offer its support to the TGA in the development of this documentation, particularly as it relates to Small to Medium Enterprises (SMES).

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<sup>1</sup> The Treasury, Achieving Best Practice Consultation with Small Business: A Guide for Government, 2012, p. 3

<sup>2</sup> Ibid., p. 5



As industry associations, including ADIA, are often the main source for businesses, particularly SMEs, when it comes to learning about new regulatory requirements, the TGA should as a matter of priority prepare materials for the specific purpose of dissemination by industry associations to their members. ADIA would gladly support the TGA in the dissemination of such materials and resources.

ADIA is encouraged by the fact that the TGA has flagged its intention to deliver SME Assist seminars on compliance with the new advertising code. As described above, SMEs have fewer resources available to them relative to large businesses. As such, guidance material should be drafted and presented in such a manner that takes into consideration these limited resources, in particular time and the ability to be aware of the latest in changes to regulatory requirements. ADIA, as the representative of an industry consisting primarily of SMEs, is pleased to offer the TGA support in the drafting of documentation targeted at SMEs.

This consultation on reforms which will support the new *Therapeutic Goods Advertising Code 2018* is the latest of a series of activities undertaken by the TGA in implementing the recommendations of the MMDR review that were accepted by the Australian Government. In doing so, the TGA has demonstrated a strong capability for undertaking robust stakeholder consultation. In this context, ADIA is confident that the advice tendered in this document will assist the TGA in developing its complaints handling process for breaches of the *Therapeutic Goods Advertising Code 2018*, and accompanying guidance materials, in a manner that consumers are protected while at the same time ensuring that businesses are not subject to unnecessary red tape.

As the TGA continues its deliberations with respect to this matter, if there is a need to seek further guidance please contact myself via email at [policy@adia.org.au](mailto:policy@adia.org.au) or by telephone on 1300 943 094.

Yours faithfully



Con Sideris  
Policy & Research Manager

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