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AANA Submission: Advertising Therapeutic Goods in Australia: Consultation Paper

The Australian Association of National Advertisers (AANA) welcomes the opportunity to comment on the above consultation paper, dated June 2010, on behalf of our advertising, marketing and media members on the advertising of therapeutic goods in Australia.

Introduction to AANA

AANA, the peak body for over 80 years, represents the common interests and obligations of companies across all business sectors involved in the advertising, marketing and media industry; membership includes category leaders in the therapeutic products sector. AANA also serves to protect the rights of consumers in ensuring advertising and marketing communication is conducted responsibly, including through its development and administration of industry codes and the self-regulatory system.

Advertising and marketing plays a fundamental economic role in society and contributes significantly to the Australian economy annually. It is the driver of consumer choice and, by providing information and promoting competition, helps consumers get better value for money. It enables innovation to be brought to market and stimulates economic growth and jobs.

AANA has a history in supporting good regulation and self-regulation for therapeutic goods advertising including through our role on the Therapeutic Goods Advertising Code Council.

AANA supports policy and regulatory developments to address community and industry concerns regarding the current regulation of therapeutic goods advertising. AANA strongly supports and drives effective self-regulatory initiatives that enable advertisers to respond to market and social challenges.

AANA promotes responsible advertising through its involvement in developing appropriate regulatory (legislative) and self-regulatory mechanisms.

AANA welcomes the recognition and support by government for self-regulation as outlined in the *Position Paper on the Promotion of Therapeutic Goods* to achieve policy outcomes. Self-regulation in advertising is broadly recognized and supported by government as an

effective mechanism for achieving health policy outcomes and one that should be considered before legislated regulation is introduced.

AANA welcomes the opportunity to review the current advertising arrangement for therapeutic goods to achieve better understanding by consumers and industry, as well as to provide an effective structure and procedures that are cost-effective while minimizing the regulatory burden for industry. The development of the regulation of advertising for therapeutic goods must recognize, and be able to support, a very diverse industry that includes large multinational companies as well as many small businesses.

In revising the regulatory arrangements for advertising therapeutic goods, AANA believes that, as good practice, an assessment of the role of advertising in relation to consumer health and wellbeing should be conducted. This is particularly important in an environment of consumer access to, and engagement with, a vast and varied body of information, especially via the internet, regarding medicines and other health products. AANA suggests that the regulation of advertising should assess the risks and benefits of various options, this position being consistent with the one expressed by the Productivity Commission in its *Review of the Regulatory Burdens on Business: Manufacturing and Distributive Trades* (2008).

Specific Comments

- *Are the current arrangements for advertising of therapeutic goods in Australian known to you? Should these be better known or understood?*

Under the *Therapeutic Goods Act 1989* AANA is a prescribed member of the Therapeutic Goods Advertising Code Council (TGACC). AANA appreciates our ongoing membership of the TGACC and the opportunity to contribute to effective administration of the current therapeutic goods advertising regulations.

AANA, and its therapeutic sector members, well understand the current regulatory arrangements. However, we note that therapeutic goods advertisers and marketers are also subject to a range of other legislation and self-regulatory schemes.

AANA's advertising self-regulatory scheme came into operation in 1997 following extensive consultation with consumer, industry and government representatives. The scheme currently includes four voluntary codes, all of which also apply to the therapeutic goods advertisers:

- *Advertiser Code of Ethics*
- *Food & Beverages Advertising and Marketing Communications Code*
- *Advertising & Marketing Communications to Children Code*
- *Environmental Claims in Advertising and Marketing Code*

Any observed non-conformance with any of the AANA codes is complaints based. It offers the public a means of participating in facilitating compliance with the codes across the broadest range of advertising and marketing communications. The Advertising Standards Bureau (ASB), established by AANA, independently administers complaints handling in accordance with procedures set down in the codes. The AANA codes provide members of the public with a free, open and transparent mechanism to address concerns about advertising and marketing communications. The ASB also provides advertising complaints

administration for a number of other industry sector codes and initiatives as well as a single point of contact for consumers who have concerns regarding advertising. Further information is available at www.adstandards.com.au .

The ASB receives and processes complaints regarding therapeutic goods advertising as they relate to AANA codes. Between January 1997 and 18 August 2010 48 complaints in the health category (many for therapeutic goods) were considered by the Advertising Standards Board. If the subject of the complaint falls under the purview of the therapeutic advertising regulations the complaint is referred to the relevant complaint mechanism for action.

AANA recognizes that the size and diversity of businesses in the therapeutic goods sector, retailers and consumers requires ongoing awareness and education initiatives.

- *Do you have comments or complaints about the current advertising arrangements*?

AANA supports a specific advertising code of practice that applies to therapeutic goods in addition to co- and self-regulatory mechanisms in relation to administration, including of complaints handling. AANA's concern with the current advertising scheme is its fragmented framework and the inappropriate dealing of 'efficacy' matters by the advertising complaints panel as noted in the consultation paper.

AANA acknowledges the various sectoral industry associations connected with therapeutic goods and their respective self-regulatory mechanisms that have an important role in effecting the advertising standards. However, AANA believes that a more centralized approach would provide greater clarity and efficiencies for industry as well as consumers. The current multiple complaint handling options are not ideal and the whole framework lacks transparency for the Australian public. The Advertising Standards Bureau, for example, provides a centralized complaint 'portal' for a number of self-regulatory initiatives. Further information is available at www.adstandards.com.au.

In relation to 'efficacy' AANA considers that this matter should **not** be a matter that is considered by an advertising complaints panel. AANA notes that therapeutic goods are subject to market authorization, including for evidence of efficacy. The regulator should always appropriately address any questions on efficacy. AANA considers that guidance on the application of the *Therapeutic Goods Advertising Code* may be useful to clarify how this matter is dealt with. For example, if pre-approval is required the matter can be raised at this point. AANA also believes that an unnecessary regulatory burden is currently placed on advertisers as they are subject to numerous compliance mechanisms, eg pre-approval, complaints and TGA monitoring, all with the potential for different outcomes. Without evidence of market failure, to the detriment to the Australian community in relation to current advertising of therapeutic goods, AANA would advocate for a system that reduces the regulatory burden on advertisers.

- *Should the current pre-approval process for advertising be retained? If so, should all forms of advertising be considered in this process*?

Both pre-approval and pre-vetting processes are useful tools to promote regulatory compliance and confidence in regulatory compliance in a diverse therapeutic goods market. The current system is inequitable across all forms of advertising and marketing communications and no evidence has been presented that indicates why broadcast media requires more stringent regulation that other forms of advertising.

AANA considers that the current arrangements should be re-considered due to the monumental shift currently underway in advertising and marketing practices. Implementing better industry practice and self-regulatory measures will be increasingly important given the speed of evolution (and revolution) of the online and digital environment in particular and the acknowledged difficulties of implementing and maintaining adequate legislative protections. AANA would not support arrangements that required pre-approval for all advertising material as this is practically not possible with the range of advertising and marketing communications within a campaign or new forms of advertising eg social media. It would also be at an unaccpetable cost and imposition to commercial operations.

AANA suggests consideration be given to implementing a dual process that includes both voluntary pre-approval and pre-vetting options. For example, an advertiser may wish to assure compliance by opting to have advertising pre-approved – such approved advertisements would not be subject to the full complaints process (refer to comments above). Given the significant resources required for some media campaigns this option is likely to be attractive to those advertisers to reduce risk. However, if pre-approval is obtained this should be the 'stamp' of regulatory compliance – complaints should only be accepted if the advertisement differs from that approved.

Pre-vetting could also be available on a voluntary basis as an advisory service to advertisers, particularly those that advertise in non-specified media. This option should reduce the likelihood of an advertisement receiving a complaint and would be a matter taken into consideration in determining a complaint – therefore further reducing the risk to advertisers and improving information provided to consumers. AANA notes that there are currently commercial professional advisory services available to advertisers in addition to member services provided by sectoral industry associations. AANA suggests that the detail of how pre-vetting is undertaken requires further consideration.

- *Should the TGA publish on its website information related to products removed from the Australian Register of Therapeutic Goods*?

AANA considers that this would be useful information for the public, however, it should apply to all products removed from the register. Further consideration is needed on what other information is provided eg the reason for the removal.

- *Should the CRP be reconstituted as an independent body*?
- *Should the CRP consider complaints about all forms of advertising*?

AANA believes that the CRP currently operates as an independent committee. However, AANA would support further consideration of a cost and time efficient, independent industry arrangement that deals with all complaints.

- *Should civil penalties apply for breaches of the regime*?

AANA would support the introduction of appropriate civil penalties as a 'last resort' in a compliance and enforcement framework for advertising regulation. The introduction of appropriate civil penalties in proportion to the risk to public health resulting from non-compliance to advertising regulations.

AANA looks forward to the outcomes of this consultation and further involvement in the development of reformed regulatory arrangements for therapeutic goods.

Yours sincerely

Scott McClellan
Chief Executive Officer

27 August 2010

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