Medical Technology Association of Australia

Therapeutic Goods Administration
Advertising Therapeutic Goods in Australia

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Medical Technology Association of Australia Limited
Level 12, 54 Miller Street
North Sydney NSW 2066 Australia
P: (02) 9900 0650
E: reception@mtaa.org.au
www.mtaa.org.au

MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

Contents

1. Executive Summary

The Medical Technology Association of Australia welcomes the opportunity to respond to the Consultation Paper on *Advertising Therapeutic Goods in Australia*. The regulation of advertising needs to balance a number of competing interests – the desire of a manufacturer or supplier of a product to build market awareness of the product, the regulatory agencies in ensuring that the claims made are accurate, not misleading, and consistent with marketing approval, and the consumer in receiving information that will assist in understanding the product and its impact.

Regulation also needs to be responsive to societal changes. Information is communicated through many different media including traditional channels such as print, radio, and television. However, traditional media is no longer the only source of promotional material. In the case of medical technology, a considerable amount of information is now available via the internet, through social media such as Facebook, blogs and Twitter. Often this information is not generated by the sponsor with the best information about the product. The sponsor often has little control over the content and limited opportunity to respond and correct the information.

MTAA does not accept that there should be a differentiation in treatment of advertising depending on the medium through which it is transmitted. Further, MTAA does not accept that there should be different requirements for different therapeutic products. MTAA addresses relevant questions raised in the Consultation Paper but also raises broader issues for consideration.

In devising a regulatory framework for the 21st century, MTAA **recommends**:

- Consistency of treatment between therapeutic products
- Consistency of regulation of advertising across all media
- A broadened definition of *advertisement*
- An extension of coverage to include social media
- Provision of product information on medical devices, directed to consumers.

2. About the Medical Technology Association of Australia and the medical technology industry

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday items such as bandages and syringes, to high technology items such as cochlear implants and cardiac defibrillators and diagnostic imaging equipment. The medical technology industry had sales in Australia of more than $7 billion in 2008/2009 and employs more than 17,500 people. It is strongly research-based, often

working closely with healthcare professionals to design and develop products for improved patient benefit.

The majority of medical technologies are not supplied direct to consumers. They are provided to hospitals, doctors and clinics. A small number of consumable items for consumers are advertised directly, such as wound care products and contact lens solutions.

3. How advertising of medical devices is regulated now

There are approximately 10,000 medical technology products on the Australian Register of Therapeutic Goods (ARTG). The advertising of these products is regulated through a combination of the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Advertising Code* (TGAC), and the industry code of practice (MTAA Code of Practice now in its 5th edition). The industry code is focused on the advertising of products to healthcare professionals and those with responsibility for the purchasing of medical devices. The TGAC is directed to advertising to consumers.

An advertisement is defined in the *Therapeutic Goods Act 1989* as *any statement, pictorial representation or design intended to promote the use of supply of goods*.

Advertisements for medical devices do not need approval in Australia unless they are advertisements with restricted representations[1]. An advertisement may only contain a restricted representation with the prior approval of Therapeutic Goods Administration (TGA) on recommendation from the Therapeutic Goods Advertising Code Council (TGACC)[2]. A restricted representation refers to a disease, condition, ailment or defect listed on Appendix 6 Part 2 of the TGAC. An advertisement must not contain a prohibited representation which is a representation regarding the treatment, cure or prevention of a small number of specified diseases.

The TGAC imposes broad principles on the content of advertisements for therapeutic products including that they contain correct and balanced statements and claims which a sponsor has verified, not arouse unwarranted or unrealistic expectations of product effectiveness, and not mislead or be likely to mislead.

A person may make a complaint about an advertisement of a therapeutic product to the Complaints Resolution Panel (CRP) where the advertisement is published in specified media and where the complainant believes the advertisement to be in breach of the TGAC[3]. Specified media includes mainstream media (magazines or newspapers for consumers), broadcast media, films, or displays including posters (in public areas such as shopping malls).

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[1] Section 3(3) *Therapeutic Goods Advertising Code 2007* (TGAC)
[2] Appendix 6, Part 2 TGAC
[3] Appendix 4, TGAC and Part 6, Division 3 *Therapeutic Goods Regulations*

4. Comments on the Consultation Paper

The Consultation Paper seeks comments on a number of options to reform current arrangements for the regulation of therapeutic goods advertisements. Specifically the Consultation Paper seeks to inform the development of advertising arrangements that are clearer and simpler, with reduced inconsistencies between advertising requirements for different types of therapeutic goods, and more effective sanctions for breaches of advertising requirements. The Government's stated objectives are to achieve a regulatory framework for advertising therapeutic goods that is more efficient, effective, transparent and consistent than the current system, that balances the risks and benefits, and that adopts a risk management approach complementary to that used for regulating therapeutic goods.

MTAA takes the view that the review of regulation of advertising of therapeutic goods also provides the opportunity to reconsider the nature of regulation of advertising in the 21st century with the different demands that arise from the use of new media as well as the internet, as vehicles for product promotion and commentary. Further, MTAA believes that the review also provides an opportunity to examine the nature of information that can be provided direct to consumers to more adequately inform consumers of healthcare products, specifically medical technology products, about the products themselves, their use and application.

5. How the advertising of medical devices is regulated in other GHTF countries

The Canadian system is similar in concept to the Australian system but with significant differences. The Canadians have a system of non-mandatory preclearance for promotion to professionals and material related to prescription drugs or vaccines to consumers. The geographic location of Canada produces an anomaly which is a problem for the average Canadian citizen. While the Canadian legislation forbids direct to consumer advertising for drugs and devices through Canadian media, as the American media networks, print and electronic, are easily available in Canada, and the US system allows this form of promotion, many Canadians are exposed to it. The Canadian system does not have arbitrary notions of "above the line" and "below the line" advertising.

In the European Union the advertising of therapeutic products is regulated primarily through the unfair trading directives, directed both to consumers and to competitor comparative claims[4]. There is some emphasis on using the Eucomed Code of Practice as well as codes adopted by the individual industry associations that are members of Eucomed. Any advertising of medical technology has to be consistent with the device's intended purpose

[4] Directive 2005/29/EC of 11 May 2005 concerning unfair practices in the internal market; Directive 2006/114/EC of 12 December 2006 concerning misleading and comparative advertising

and claims have to be capable of being verified. As in Australia, direct to consumer advertising is also not permissible in most cases.

In the United States, the Food and Drug Administration (FDA) regulates the labelling of medical devices and the advertising of restricted devices. Restricted devices in the US are different from the Australian concept of a restricted claim. They are medical devices that have received FDA approval but are restricted as to their sale, distribution or use. An advertisement for a restricted device must include a statement of the intended use of the device and relevant warnings, precautions, side effects, and contraindications. The relevant legislation, the Federal *Food, Drug, and Cosmetic Act* (FD&C Act) also specifies that restricted medical device advertisements must not be false or misleading and must reveal the facts about the product being advertised, including the consequences that can result from the use of a product as suggested in an advertisement.

In addition to the oversight by the FDA of restricted devices, the Federal Trade Commission (FTC) regulates the advertising (but not labelling) of all other medical devices[5]. It prohibits advertising that is false or misleading and requires substantiation of all claims that are made in advertisements. With respect to advertising of medical devices the FTC has defined substantiation as requiring balanced, scientific evidence in the form of well-controlled clinical studies.

The Office of Compliance within FDA's Center for Devices and Radiological Health is responsible for the surveillance and enforcement of violations in the marketing of promotional materials of all medical device companies. The Office reviews trade complaints about promotion from competitors, health care professionals and consumers.

As noted above, in the United States it is permissible to advertise medical devices direct to consumers. The industry association, AdvaMed, has published *Guiding Principles for Direct-to-Consumer Advertising*. The principles are designed to promote advertising practices that[6]:

- Encourage discussion between patients and their healthcare professionals
- Use consumer-friendly language appropriate for the intended audience
- Present risk information in lay terms and in a manner free from distraction
- Appropriately educate healthcare professionals before an ad campaign launches
- Support submission of new television advertisements for restricted devices to FDA at the time of broadcast release

[5] Sections 12-15 of the *Federal Trade Commission Act*
[6] Peter Rixon, "Advertising of devices in the US 'can empower patients' " Clinica published online 11.05.2009 at http://www.pjpubs.com/pop_newstream_story.asp?xml=y

- Provide appropriately disclosed, honest and substantiated endorsement, and testimonials that represent a typical patient experience.

MTAA is not advocating a move to direct-to-consumer advertising, but does support a mechanism by which consumers may be provided with accurate and relevant information about a medical device. The broad principles outlined above for DTC advertising are also appropriate in this context.

6. Building an appropriate model for regulation of advertising

6.1 Issues for consideration

MTAA has considered a series of core questions to inform the development of a more relevant regulatory model:

- What is an advertisement?
- What should be the requirements for an advertisement directed to a healthcare professional?
- What should be the requirements for an advertisement directed to a consumer?
- Does there need to be a pre-approval process for any advertisement of medical technology?
- What should be the complaints process for a breach of advertising regulations?

6.2 What is an advertisement?

The proposed *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006* (Rule), developed as part of the ANZTPA reforms, introduced some concepts which MTAA recommends be adopted in the current reforms. The first of these relates to the definition of *advertisement*. MTAA supports the use of the broader definition proposed in the Rule:

> *'**advertisement**', in relation to a therapeutic product, means any communication that promotes or discourages the use, sale or other supply of the product, whether or not the communication is in conjunction with the supply of a service or identifies the particular product or service, but does not include:*
> *(a) a product label; or*
> *(b) a communication of any of the following kinds:*
> *(i) corrective advertising;*
> *(ii) a retraction;*
> *(iii) bona fide news, a bona fide editorial or a bona fide public interest or entertainment program;*
> *(iv) bona fide educational, research or professional advice*.

This definition is more accurate, more focused, and more flexible than the current definition. There are many examples where a company might be

caught under the existing definition of 'advertisement' because of its breadth. The definition of 'advertisement' in the current TGAC is very narrow. It would capture as an advertisement, for example, a company responding to comment made on a social networking site, or in a blog. The response is making a *'statement. ..however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods'*. The response may be for the purpose of correcting erroneous statements made by the author of the social networking posting or blog. It is in the interests of consumers of therapeutic products that erroneous statements are corrected.

MTAA accepts that there is a difference between paid advertorials and educational/informational material. This differentiation is not made in the current definition, again a disincentive to provide useful, objective information to consumers.

MTAA proposes an expansion of the definition in the Rule by adding into paragraph (b) an additional provision to enable a correction to a news or public affair item.

At Attachment A is a posting from a popular Australian diabetes blog that published misinformation about 'Safety Alerts'. The company referred to responded in this instance as the posting was talking about an issue rather than a product. However at times there are also cases where misinformation is published about products where the company would want to respond but is precluded from doing so at present because it may be seen as 'promoting' a product.

A second example at Attachment B, is a recent story from www.6minutes.com.au on how a media report on bisphosphanates led to many people stopping medication. While this relates to a medicine, it provides a good example on how damaging incorrect information can be.

Another recent example which received publicity via Facebook page and a story in mainstream media concerned deep brain stimulation treatment for two sisters. The site and story both refer to the need for surgery overseas. The information is incorrect astreatment for their condition is available in Australia. However the company that supplies the product which is used in the treatment was unable to respond under the existing legislation without appearing to 'promote' the product.

In the United States there are a few examples of medical device companies using social media to promote a product. However the media do not readily lend themselves to the advertising of complex devices and procedures. The concern is more that companies should have the capacity to respond with factual information and clarification when incorrect information is published by third parties.

MTAA supports the broader terminology of *'communication'* in the definition in the Rule as it is more all-encompassing and includes the wide variety of social media now in use.

The exclusions to the definition in the Rule might not be sufficiently wide to include statements made in compliance with regulatory obligations, such as an announcement to the Australian Stock Exchange. Extension of the carve-outs for this purpose should also be considered.

6.3 What should be the requirements for an advertisement directed to a healthcare professional?

Advertisements directed to healthcare professionals are primarily published in specialist clinical and professional magazines and newsletters. Healthcare professionals are also informed about new products through direct interaction with a company offering training on a new product, or through an exhibition at a trade show, often held in conjunction with a clinical scientific meeting.

As a result most healthcare professionals learn about new products and their features in a clinical or educational setting. The interaction between healthcare professionals and medical technology companies is circumscribed by the MTAA Code of Practice.

MTAA recommends that the industry Code continue to be the primary regulator of advertisements directed to healthcare professionals. Issues such as the making of comparative claims are dealt with under the Code. The complaint is dealt with through the independent complaints process.

6.4 What should be the requirements for an advertisement directed to a consumer?

There is benefit to the consumer to have informed, accurate information about healthcare products which will be used in, on, or by the consumer. This information assists the consumer to make better-informed decisions about their health care. The information can also be used by the consumer to frame more informed questions to put to the health care professional responsible for their treatment.

Under the current regulations, medical technology companies are not able to provide informational material on products direct to consumers. MTAA strongly supports reform to the regulations in this area. This could be addressed through an expansion of the carve-outs in the Rule (referred to in paragraph 6.2) to enable provision of appropriate informational material.

There is an anomaly at present where a healthcare professional may display a wall poster with product information, provided the wall poster does not mention a brand name. The same information, with brand name included, can be provided by the healthcare professional to the patient, but only during consultation.

MTAA argues that a more open approach will enable consumers to have access to better quality information to counterbalance inappropriate or incomplete information. It can also be used to support more detailed informed

financial consent where there is a patient co-payment. Medical technology companies want to be able to provide ongoing and updated, relevant information rather than rely on 'news breaks' on new technologies which is the only way to get generic new product information to consumers at present.

A consumer advocate has pointed out[7] that "[c]onsumers seek the opportunity to give informed consent. In order to do this they need to properly understand what treatment and tests are being offered, and on what evidence a health care professional is recommending them".

There is strong evidence to support the positive outcomes for patients when provided with consumer information. A metadata analysis of research on positive outcomes was undertaken in the context of medicines[8]. There is no reason to expect different, or lesser, outcomes when patients are provided with written, relevant, informative, consumer product information about a medical device.

6.5 Does there need to be a pre-approval process for any advertisement?

MTAA argues that the present arrangements for approval of advertisements of medical devices should be retained to the extent that approval is limited to advertisements making a restricted representation. In all other cases medical device advertising should be exempt from pre-approval as it is now. The sponsor of a medical device must comply with the Essential Principles under the *Therapeutic Goods Act 1989*. If the sponsor does not comply then the product will not be registered or the sponsor may be prosecuted for non-compliance.

The Essential Principles provide, inter alia, that a medical device is designed and produced in a way that ensures that the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when used on a patient as intended by the manufacturer.

MTAA does not support the different treatment of advertising of products 'above the line' and 'below the line'. With the diversity of modern media this division no longer seems appropriate.

MTAA supports continued pre-approval of advertisements containing restricted representations. This may expand if the regulations are amended to permit provision of consumer product information.

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[7] Janet Spink, "Promoting quality information exchange involving consumers", *The Australian Health Consumer*, Number Three 2002-03, page 32 at page 34

[8] National Council on Patient Information and Education, "The Benefits of Consumer Medicine Information" at http://www.talkaboutrx.org/documents/benefits_cmi.pdf accessed 25 August 2010

6.6 What should be the complaints process for a breach of advertising regulations?

Much of the activity of the CRP appears to be focused on the assessment of competitor claims. This is time consuming and questionable in merit. MTAA recognises the cost-effectiveness of a complaints resolution body such as the CRP but questions its capacity to quickly and fairly resolve what can be technical legal claims. Other options include TGA handling competing claims if relevant to a claim regulated by TGA, or the ACCC if the claim has significant commercial impact.

The penalties for compliance with the advertising regulations need to be considered. In addition to the right to demand removal of an advertisement, a breach of the advertising regulations could be handled in accordance with the complaints process under an industry code of practice. Breaches of the codes can attract significant penalties but also provide a range of other sanctions. One option, yet to be considered by the therapeutic industry associations, is to have one complaints resolution mechanism applicable to all complaints brought against a therapeutic industry company.

However for initial reform in this area to be effective, the therapeutic industry codes must be aligned and non-members of industry associations equally bound by them. Work on these issues is being undertaken by the Working Group on Promotion of Therapeutic Products. The effectiveness of this as a solution will need to be considered once the Working Group has completed its task to ensure that there are mechanisms which could also apply to enforcement of breaches of advertising regulations.

Another mechanism which MTAA proposes is that that an equivalent to the current NCAR process could be investigated, to ensure that notification of the withdrawal of an advertisement of a product in another jurisdiction is acknowledged and implemented in Australia. This should extend to the withdrawal of internet advertising of inappropriate products.

7. Response to consultation questions

7.1 Overall awareness of the arrangements for advertising of therapeutic goods

MTAA members are aware of the current arrangements for advertising of therapeutic goods although these are not well understood in every case.

MTAA's comments about the current arrangements are set out in section 6 of this submission

7.2 Using the advertising arrangements

Advertisements for medical devices do not require approval unless they address a restricted representation. MTAA has received no comment from

member companies on the suitability or otherwise of the current arrangements but supports the current arrangements for approval of advertisements with restricted representations, provided that the coverage of the representations is reviewed regularly. MTAA also supports the provision of consumer product information to assist consumers to understand the product, its use, and precautions that might be needed.

7.3 Pre-approval process

The pre-approval process for therapeutic products that are not medical devices or medicines should have an enhanced evidence base to ensure that product efficacy can be fully assessed. Standards of efficacy should become more consistent for all therapeutic products.

There should be no differentiation in the form of media in which the advertisement appears. In addition to traditional media MTAA also proposes that newer media such as the internet, and social media like blogs be included.

7.4 Complaints mechanisms

MTAA supports improved transparency of availability of information to consumers and others (subject only to respect for commercially confidential information). Once the process which leads to removal from the ARTG has been completed, publication of the removal of products from the ARTG will improve the transparency. The reason for removal should also be published.

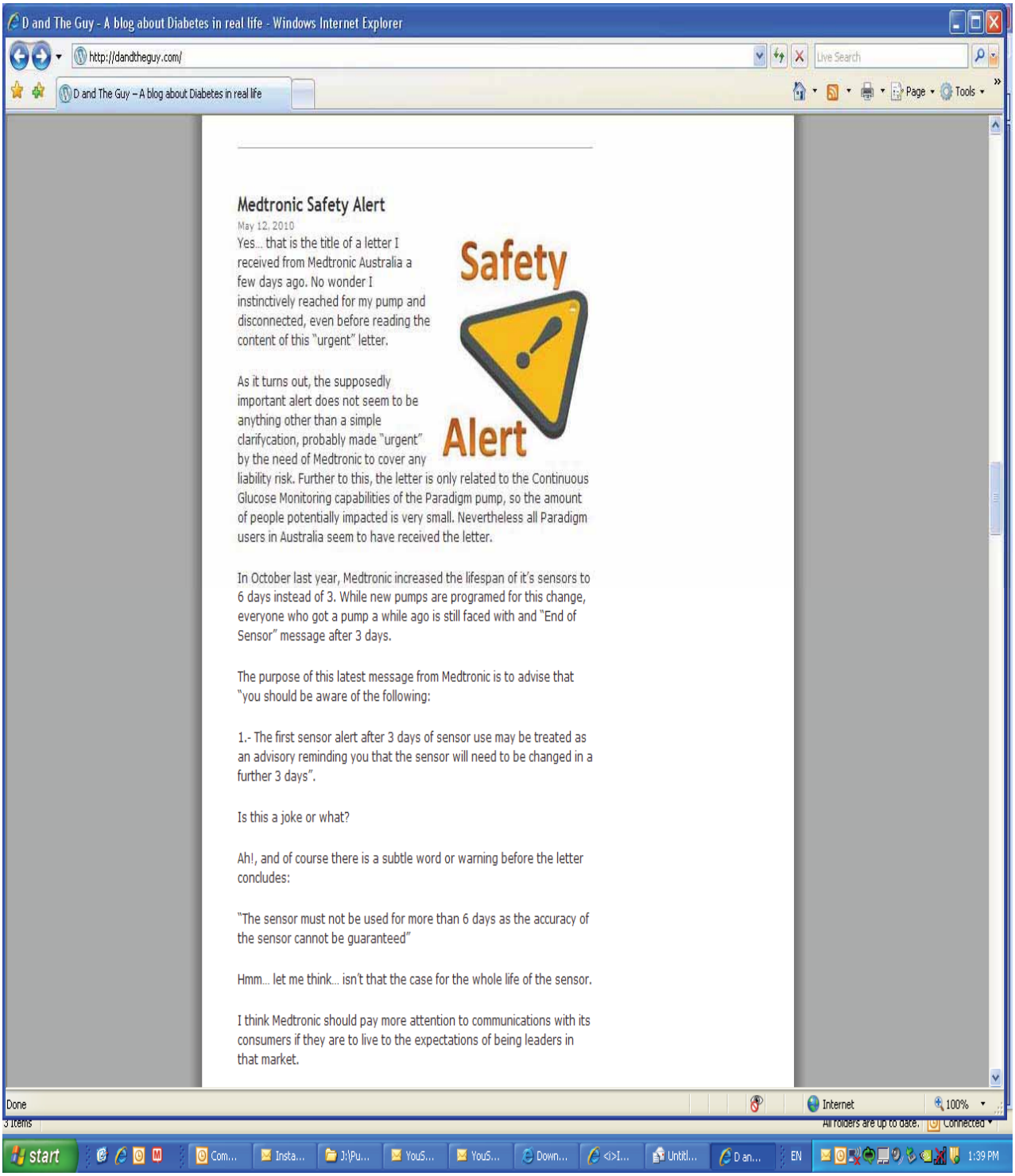
MTAA does not have a strong view either way about the need for an independent body but can understand the perceptions that those outside the CRP have that it might be compromised by its current composition. If independence strengthened the credibility of the decision-making process then there is merit in it and MTAA would support it.

As previously stated, there should be no differentiation in consideration of complaints based on the form of media in which the advertisement appears. All should be treated equally. If some complaints are trivial or vexatious, these should be weeded out of the process through a regulation that allows for them to be dismissed without referral to the CRP.

The range of penalties should be expanded to provide the CRP a full range of options. Under the MTAA Code of Practice, for example, penalties for a breach range from an order to cease an activity, recall and destroy offending material, issuing a retraction (including corrective letters and advertising), to imposition of a sliding scale of fines. A similarly broad range of sanctions should be available to CRP, including increased fines for repeat offences.

As outlined earlier in this submission, MTAA also supports investigating the sharing of information with other jurisdictions where action has been taken in relation to an advertisement.

Attachment A



Attachment B