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## **Abstract**

The Therapeutic Goods Act 1989 (Cth) constitutes an important segment of the consumer law regulatory regime applying to complementary and alternative medicine ('CAM'). This article critically evaluates that regime, concentrating on the level of evidence required to justify health claims for registration or listing of CAM products and in relation to the advertising of such products. It identifies the anomalies that arise from the application of the current regulatory structure, and offers conclusions and recommendations intended to improve the present position.

## **Keywords**

complementary and alternative medicine, Therapeutic Goods Act, health claims, consumer regulation

# REGULATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE: INTERPLAY OF THERAPEUTIC GOODS LEGISLATION AND CONSUMER LAW

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## ABSTRACT

*The Therapeutic Goods Act 1989 (Cth) constitutes an important segment of the consumer law regulatory regime applying to complementary and alternative medicine ('CAM'). This article critically evaluates that regime, concentrating on the level of evidence required to justify health claims for registration or listing of CAM products and in relation to the advertising of such products. It identifies the anomalies that arise from the application of the current regulatory structure, and offers conclusions and recommendations intended to improve the present position.*

## I INTRODUCTION

This article will consider and analyse a segment of the consumer law regulatory regime applied by the *Therapeutic Goods Act 1989* (Cth) ('TGA') which relates to complementary and alternative medicine ('CAM'). The article will focus on the level of evidence required to justify health claims for registration or listing and in regard to advertising of CAM products. It will further consider the anomalies that arise from the application of the current regulatory structure. This analysis will lead to conclusions and recommendations about how this regulatory structure could be improved.

The TGA and the equivalent state legislation, which applies within four states,<sup>1</sup> are drafted with the legislative objective of providing for the establishment and maintenance of a national system of controls relating to the safety, efficacy and timely availability of therapeutic goods that are used in Australia, whether those goods are

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<sup>1</sup> *Therapeutic Goods Act 1994* (Vic); *Poisons and Therapeutic Goods Act 1966* (NSW); *Therapeutic Goods Act 2001* (Tas) and *Controlled Substances Act 1984* (SA).

produced in Australia or elsewhere or exported from Australia.<sup>2</sup> It is evident from the objects of the *TGA* that it is an important consumer protection measure. The definition of ‘therapeutic goods’ includes goods ‘that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use’.<sup>3</sup> ‘Therapeutic use’ is defined broadly to include ‘use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or influencing, inhibiting or modifying a physiological process in persons.’<sup>4</sup> These statutory definitions mean that the *TGA*, through the administrative body established by this legislation, the Therapeutic Goods Administration, regulates not only pharmaceuticals but also CAM substances. The objects of the *TGA* are supported by the licensing and auditing of manufacturers of CAM, including the application of the *Guide to Good Manufacturing Practice for Medicinal Products*, pre-market assessment of complementary medicines and post-market activities involving audits and testing of products.<sup>5</sup>

## II OVERVIEW OF THE TGA REGULATORY STRUCTURE IN RELATION TO CONSUMER ISSUES

CAM practitioners, manufacturers and suppliers of CAM products are subject to complex regulation under the *TGA* for the manufacturing, sale (wholesale or retail), import and export and supply of therapeutic goods. The Australian Regulatory Guidelines for Complementary Medicines provides an overview of the most important aspects of the regulatory structure.<sup>6</sup>

The provisions of ch 2 ss 9A-9E of the *TGA* require the establishment of the Australian Register of Therapeutic Goods (‘ARTG’) for registered and listed goods.

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<sup>2</sup> *Therapeutic Goods Act 1989* (Cth) s 4(1).

<sup>3</sup> *Therapeutic Goods Act 1989* (Cth) s 3 (definition of ‘therapeutic goods’).

<sup>4</sup> *Ibid* (definition of ‘therapeutic use’).

<sup>5</sup> Michael Weir, *Law and Ethics in Complementary Medicine: A Handbook for Practitioners in Australia and New Zealand* (Allen and Unwin, 4<sup>th</sup> ed, 2011) 155. Therapeutic goods do not include goods that have a prescribed standard in the *Australia New Zealand Food Standards Code* as defined by the *Food Standards Australia New Zealand Act 1991* (Cth) or goods that have a tradition in Australia and New Zealand for use as foods for humans in the form in which they are presented. These foods should not be marketed as having therapeutic properties: 165.

<sup>6</sup> Therapeutic Goods Administration, *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) (26 July 2012) <<http://www.tga.gov.au/industry/cm-argcm.htm#structure>>.

There are criminal and civil penalties for the importation, export, manufacture or supply of therapeutic goods unless they are either registered or listed goods in relation to the person, are exempt goods,<sup>7</sup> or the practitioner is given exempt status from the provisions of the *TGA*.<sup>8</sup>

### *A Registered Goods*

Registration involves an extensive appraisal of the quality, safety and efficacy of goods based upon controlled clinical trials or, if available, from other well accepted sources such as standard textbooks.<sup>9</sup> Registration is necessary for substances considered high risk and includes all prescription medicines containing ingredients included in sch 4 or sch 8 of the Standard for the Uniform Scheduling of Drugs and Poisons.<sup>10</sup> Some low-risk non-prescription drugs may be registered if it is considered necessary to ensure adequate labelling for safe use.<sup>11</sup> Registered goods are also assessed for presentation, conformity with an applicable standard and appropriateness of manufacturing process.<sup>12</sup> The Advisory Committee on Complementary Medicines ('ACCM') provides advice in relation to registration of CAM products.<sup>13</sup> Some complementary medicines are registered. Registered products can be recognised by the notation 'AUST R No xxx' shown on the label.<sup>14</sup>

### *B Listed Goods*

Listing is afforded to therapeutic goods with a perceived lower risk, usually self-selected by consumers and used for self-treatment. Listing involves a low cost streamlined electronic process for assessment of the therapeutic goods in terms of their quality, safety, presentation, manufacturing process and conformity with relevant standards under the *TGA*.<sup>15</sup> Listing does not require scientific justification of indications for product use, though a sponsor who has listed a therapeutic good may be asked to provide information or evidence to support the claim and comply with

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<sup>7</sup> *Therapeutic Goods Act 1989* (Cth) s 34.

<sup>8</sup> *Ibid* pt 3-2 div 1.

<sup>9</sup> *Ibid* s 25.

<sup>10</sup> *Therapeutic Goods Regulations 1990* (Cth) schs 3, 4.

<sup>11</sup> *Ibid*.

<sup>12</sup> *Therapeutic Goods Act 1989* (Cth) s 25.

<sup>13</sup> *Therapeutic Goods Regulations 1990* (Cth) reg 39A.

<sup>14</sup> John McEwen, 'What Does TGA Approval of Medicines Mean?' (2004) 27 *Australian Prescriber* 156, 156.

<sup>15</sup> *Therapeutic Goods Act 1989* (Cth) s 26.

the requirements (if any) of the regulations.<sup>16</sup> Most complementary medicines are listed substances. Listed substances are identified by the 'AUST L No xxx' notation on the label.<sup>17</sup>

### III RELEVANT GUIDELINES

The *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* ('Evidence Guidelines') indicate the required evidence level (general, medium and high) of an indication or claim and the evidence required to support it for both listed and registered medicines.<sup>18</sup> Registered medicines can carry claims of any level, provided the Therapeutic Goods Administration has evaluated the evidence to support the indication and approved the indication for the registered medicine.

The *Therapeutic Goods Advertising Code* ('TGAC') establishes the general requirements for advertising claims for therapeutic goods. The TGAC makes provision for pre-approval of many CAM product advertisements. The TGAC defines the diseases, disorders or conditions that cannot be referred to in advertisements for non-prescription medicines, such as sexually transmitted disease or mental illness, though these advertisements continue to be subject to the TGA and its regulations, and consumer legislation.<sup>19</sup> The most significant regulatory body that deals with complaints in relation to the advertising of CAM products is the Complaints Resolution Panel ('CRP').<sup>20</sup> Advertising directed exclusively to healthcare professionals is not dealt with under the TGAC but under the industry codes of practice promulgated by industry bodies such as the Complementary Healthcare Council ('CHC') and Advertising Services Australian Self-Medication Industry ('ASMI').<sup>21</sup> Therapeutic products marketed only to health professionals, listed in s 42AA of the TGA, or labelled as 'practitioner dispensing only', are not subject to the same advertising restrictions as those marketed to the public.<sup>22</sup>

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<sup>16</sup> Ibid s 28(6).

<sup>17</sup> McEwen, above n 14, 157.

<sup>18</sup> Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims: For Non-Registerable Medicines, Including Complementary Medicines, and Other Listable Medicines* (April 2011) <http://www.tga.gov.au/pdf/cm-evidence-claims.pdf> ('Evidence Guidelines').

<sup>19</sup> *Therapeutic Goods Advertising Code 2007* (Cth) app 6 pt 1.

<sup>20</sup> *Therapeutic Goods Regulations 1990* (Cth) pt 6 div 3 sub-div 1.

<sup>21</sup> *Therapeutic Goods Advertising Code 2007* (Cth) cl 3(1)(b).

<sup>22</sup> The controls over advertising do not apply to advice or information given directly to a patient by a health practitioner, including CAM practitioners in the course of treatment of that patient: *Therapeutic Goods Act 1989* (Cth) s 42AA(4).

#### IV TGA CODES AND REGULATIONS AND ENFORCEMENT

There are also a number of industry codes of practice that deal with pharmaceutical, over-the-counter and CAM therapeutic goods that provide benchmarks for practice, including permitted representations and a complaints procedure and enforcement, thus complementing regulation under the TGA provisions. The need for partial industry regulation is based upon the constitutional limitations of the Commonwealth in regard to regulation of therapeutic goods and the control over manufacturers of therapeutic goods.

Although the Constitution allows the Commonwealth to 'cover the field' in areas over which it has concurrent power with the States, in some cases the Commonwealth may be unable satisfactorily to cover an entire field of conduct where national action is appropriate. One example is *therapeutic goods*. Given the national trade in such goods, it might be seen as an obvious area in which the Commonwealth might want to regulate. However, the Commonwealth's reach extends only to trade and commerce in such goods which occurs between States, or between Australia and other countries, or to manufacturers which fall within the power to legislate with respect to 'foreign, trading or financial corporations'. The Commonwealth therefore cannot 'cover the field' in therapeutic goods.<sup>23</sup>

Although s 4 of the TGA refers to the objective of a national scheme for the regulation of therapeutic goods, as a result of the constitutional limitation this objective is only partially fulfilled as Queensland and Western Australia do not have mirror legislation based upon the TGA.

Under reg 5Q,<sup>24</sup> the power to pre-approve or refuse advertisements in relation to complementary medicine, and to withdraw the approval, has been delegated to the CHC and the ASMI. The CHC's power to approve advertisements is limited to advertisements for complementary medicines in mainstream print media. 'ASMI's power extends to the approval of advertisements for non-prescription medicines (including complementary medicines) containing unscheduled or Schedule 2

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<sup>23</sup> Centre for Comparative Constitutional Studies, The University of Melbourne, *Implementation Options for National Legislative Schemes in Public Health* (7 September 1999) <<http://www.nphp.gov.au/workprog/lrn/legtools/options.pdf>> 8. See also John McEwen, *A History of Therapeutic Goods Regulation in Australia* (September 2007) <<http://www.tga.gov.au/pdf/history-tg-regulation.pdf>>.

<sup>24</sup> *Therapeutic Goods Regulations 1990* (Cth).

(Pharmacy-only) ingredients to appear in all specified media including radio and TV.’<sup>25</sup>

Advertising under the *TGAC* is defined broadly to mean ‘any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods’.<sup>26</sup> The *TGAC* does not allow claims in advertising for the treatment of serious medical conditions, on the grounds that such conditions are not amenable to self-diagnosis or treatment.<sup>27</sup> The advertising regulatory framework is currently under review.<sup>28</sup>

One criticism of the current pre-approval system is the gap in the ability to prevent consumers from being exposed to advertisements for therapeutic goods that contain misleading claims. Only some products and advertising media are covered by these provisions.<sup>29</sup> Currently the requirement for pre-approval does not apply to website advertisements, which no doubt will play an increasing role in marketing, on pay TV or in relation to medical devices.<sup>30</sup> Mooted *TGA* changes look to initiate a form of pre-approval for listed products, with sponsors being required to choose pre-approved indications for ingredients from a drop-down list rather than being allowed to write their own claims in a free-text format. This may deal with this gap to some extent.<sup>31</sup>

A review of complaints made to the CRP discussed below suggests that most complaints relate either to website advertisements that have not been pre-approved or in establishing whether the substance in fact advertises a therapeutic good. Over the period of 2007-2010, CAM and over-the-counter products have been the largest component of product complaints. All therapeutic goods are required to comply with the *TGAC*.<sup>32</sup> This means that advertisements in exempt media, such as the internet, must also comply with the requirements of the *TGAC* though they do not have the advantage of a pre-approval.<sup>33</sup>

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<sup>25</sup> Therapeutic Goods Administration, *Advertising Regulatory Framework: Options for Reform* (1 May 2012) <[www.tga.gov.au/word/advertising-framework-120529.docx](http://www.tga.gov.au/word/advertising-framework-120529.docx)> 12 (*‘Advertising Regulatory Framework’*).

<sup>26</sup> *Therapeutic Goods Advertising Code 2007* (Cth) cl 2 (definition ‘Advertisement’).

<sup>27</sup> *Ibid* cl 5(2), app 6 pt 2.

<sup>28</sup> Advertising Regulatory Framework, above n 25, 35.

<sup>29</sup> *Ibid* 7.

<sup>30</sup> Advertising Regulatory Framework, above n 25, 17.

<sup>31</sup> Australian Associated Press, *Sweeping Reforms for CAM Industry: TGA* (15 February 2013) Rheumatology Update <<http://www.rheumatologyupdate.com.au/latest-news/sweeping-reforms-for-cam-industry-tga>>.

<sup>32</sup> *Therapeutic Goods Act 1989* (Cth) s 42DM.

<sup>33</sup> Advertising Regulatory Framework, above n 25, 14, 17.



### *A Therapeutic Advertising Complaints – Complaints Resolution Panel*

Complaints heard by the CRP are considered based upon the terms of the *TGAC* and the *TGA* and its regulations. Membership of the CRP consists of representatives from industry, consumers, advertising agencies, healthcare professionals and government.<sup>34</sup> The CRP considers all complaints made, including complaints about advertisements that have been pre-approved before publication. As discussed below, a common complaint relates to the scientific basis for claims made in regard to therapeutic goods (typically CAM products).

Evidence is assessed by the CRP pursuant to s 4(1)(b) of the *TGAC*. This requires advertisements for therapeutic goods to ‘contain correct and balanced statements only and claims which the sponsor has already verified.’ Section 4(2)(c) of the *TGAC* further prohibits representations that ‘mislead, or [are] likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions.’

Clause 4(4) of the *TGAC* states:

Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed. Publication of research results must identify the researcher and financial sponsor of the research.

Although there is no specific test of the required quality of evidence to support claims, a review of the CRP’s decisions – virtually all of which favour complainants – suggests that, in considering evidence provided by an advertiser, a strict test is applied in regard to the evidence required to justify advertising claims. As a general rule, a claim made in relation to CAM aimed at members of the public, whether on a website or in the print or electronic media, necessitates a high level of scientific evidence to avoid a finding that the *TGAC* has been breached.<sup>35</sup> Where an advertiser presents little or no evidence to support the claims made, often in ignorance of their obligations under the *TGAC*, the CRP is likely to uphold the complaint.<sup>36</sup> Where unpublished studies and research results are presented for consideration in CRP hearings, this evidence is likely to be deemed insufficient from the perspective of the

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<sup>34</sup> *Therapeutic Goods Regulations 1990* (Cth) reg 42T.

<sup>35</sup> See, eg, the decisions of the CRP examined below.

<sup>36</sup> See, eg, *MD Cosmedical Solutions*, Complaints Resolution Panel Determination, Complaint 2012-040-010 (16 August 2012).

CRP,<sup>37</sup> again suggesting the need for high quality scientific research to satisfy the terms of the TGAC.

*Biomed Australia Pty* involved internet advertising of a 'Vega machine'.<sup>38</sup> The advertisement represented that this machine could test for allergies. The advertiser provided 'scientific evidence' for its claims based upon some studies about this equipment as well as referring to a successful court case. The evidence was rejected by the CRP on the basis that the studies were not published or subject to peer review, which itself is a fairly liberal requirement owing to the abundant nature of published research available in regard to health products. The CRP stated: 'On balance, the CRP did not consider them to constitute clear or persuasive evidence, or good quality evidence, of the therapeutic benefits referred to in the advertisement.'<sup>39</sup>

The decision of *Kanion Nutrilife Australia Pty Ltd* involved a complaint about representations made regarding the therapeutic benefits of traditional Chinese medicine advertised on a website.<sup>40</sup> The advertiser provided summaries of references for consideration by the Panel. The advertiser also suggested that the evidence upon which they relied was traditional use with some mixing of traditional and western concepts. The CRP made the following comment:

The CRP also noted that product claims that are based only on evidence of use in traditional medicine (which appeared to be the case for some, though not all, of the advertised products) must be expressed in a way that clearly conveys to consumers that they are based on such evidence. Evidence that a product has been traditionally used for a particular purpose is not evidence that it is effective for that purpose and cannot support claims of efficacy in advertisements to consumers. Rather, evidence that a product has been traditionally used for a particular purpose is evidence only that it has been traditionally used for that purpose. Advertisements that contain claims based only upon evidence of use in traditional Chinese medicine must state explicitly that those claims are based only on such evidence, or they are likely to be misleading.<sup>41</sup>

The CRP determined that the TGAC had been breached and ordered the representations to be withdrawn. It would seem that a major issue in this decision

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<sup>37</sup> See, eg, *Biomed Australia Pty Ltd*, Complaints Resolution Panel Determination, Complaint 2010-01-016 (20 May 2010).

<sup>38</sup> *Ibid* [17].

<sup>39</sup> *Ibid*.

<sup>40</sup> Complaints Resolution Panel Determination, Complaint 2011/11/023 to 2011/11/028 (5 April 2012).

<sup>41</sup> *Ibid* [20].

related to a lack of clarity about whether the advertiser was relying upon traditional or scientific evidence.

In *Brauer Hot Flush and Menopause Relief*, a homoeopathic product advertising hot flush and menopause relief was subject to a complaint that there was no evidence the product provided any relief for menopause.<sup>42</sup> The advertising on the internet noted the product was homoeopathic. The evidence provided complied with the *Evidence Guidelines* and included an amount of homoeopathic evidence. The CRP concluded:

Traditional homeopathic evidence is not evidence that a product is efficacious in providing benefits such as the relief of menopause symptoms. It is only evidence that a product or its ingredients have traditionally been used in homeopathy for this purpose. If representations based only on traditional homeopathic evidence are to comply with sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code, then the advertisement must clearly convey that those representations are based on traditional homeopathic evidence, and that the product is homeopathic in nature.<sup>43</sup>

In *Brauer Natural Medicine Pty Ltd*, the CRP stated:

[I]f evidence is to comply with the Code, then the advertisement must clearly convey that those representations are based solely on traditional homeopathic evidence, and that the evidence is of traditional use and not of actual efficacy. The advertisement should not convey that the product is of demonstrated efficacy for a therapeutic purpose, but rather that it has traditionally been used for that purpose.<sup>44</sup>

*Bayer Australia Pty Ltd* involved internet advertisements containing representations of the performance of a product that included a reduction in tiredness and stress.<sup>45</sup> The advertiser relied upon scientific evidence for the claims made. The CRP found the claims made breached the *TGAC* on the following basis:

18. Two studies, the *Caroll et al.* study and the *Kennedy et al.* study appeared to be most relevant to the advertised product and to the claims made in the advertisement, and were the primary studies relied upon by the advertiser. On reviewing this material, the CRP observed that:

a) the *Kennedy et al.* study included results in relation to ‘mental tiredness’ and not to ‘tiredness’ in a more general sense;

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<sup>42</sup> Complaints Resolution Panel Determination, Complaint 2011/04/026 (19 May 2011).

<sup>43</sup> *Ibid* [13].

<sup>44</sup> Complaints Resolution Panel Determination, Complaint 2012/03/002 (3 May 2012) [13].

<sup>45</sup> Complaints Resolution Panel Determination, Complaint 2010-10-017 (17 February 2011).

b) the *Caroll et al.* paper did include results related to a reduction in tiredness, but these results were (as acknowledged by the advertiser) not statistically significant;

c) the *Caroll et al.* paper utilised subjective outcome measures, in the form of a 'questionnaire and self-report package' at days 1 and 28 of the study only;

d) both studies involved outcome measures made at least 28 days after the commencement of intervention; and,

e) both studies were conducted only on male subjects.

19. ...Given the very modest nature of the evidence provided by the advertiser, the CRP was of the view that even modest claims regarding concentration and mental tiredness would be misleading unless qualified by reference to the period of use required for any possible benefits to accrue.

20. The CRP also noted that 'mental tiredness' was not the same as 'tiredness' in a more general sense.

21. The CRP was therefore satisfied that the claims that the advertised product was clinically or scientifically proven to have benefits in relation to concentration, tiredness, or stress, or that it could have immediate or rapid benefits in relation to concentration, tiredness, or stress, were unverified, likely to arouse unwarranted expectations, and misleading.<sup>46</sup>

In *Dr Ken Harvey and High Tech Health Pty Ltd*, a complaint was made about an advertisement for the benefits of a transcutaneous electrical nerve stimulation ('TENS') machine.<sup>47</sup> The CRP stated:

The CRP considered the evidence provided by the advertiser. The papers collectively concluded that there is some evidence for TENS machines in relation to pain relief, but more investigation is needed, and definitive proof of efficacy and safety requires formal investigation in appropriately designed clinical trials. Although the evidence provided suggested TENS machines were able to provide some pain relief, the CRP did not consider the evidence was conclusive nor did this evidence adequately support the claims 'relieve aches and pain' 'ease arthritic pain' 'reduce fluid retention and swelling' 'cankles' or 'aid fast recovery from muscular injury.'

The CRP considered that the advertisement was in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code, and found this aspect of the complaint to be justified.<sup>48</sup>

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<sup>46</sup> The basis of the decision was not to reject the scientific evidence entirely but that the evidence related to mental tiredness but did not prove the specific claims about 'tiredness'. Ibid [18]-[21].

<sup>47</sup> Complaints Resolution Panel Determination, Complaint 2010-02-027 [16].

In *Dr Ken Harvey and Erectomax*, the advertisement of a male hormone product was considered.<sup>49</sup> The advertisement suggested the product had the support of clinical trials. Specificity of claims was an issue here too. This evidence was considered to be insufficient on the basis that:

- The evidence was of traditional use not scientific evidence;
- One scientific study was too small to be persuasive and was deemed a preliminary study; and
- One scientific study was not published or peer reviewed.<sup>50</sup>

Decisions of the CRP suggest it is concerned at the growing use of the words 'clinically proven' in advertisements for therapeutic goods, when these words are not supported by an adequate and appropriate body of evidence that relates to the specific product (and not merely to a similar product or ingredient) to which the advertisement refers. In complaint 2008-02-005, the CRP stated:

The CRP also noted the use of the words 'clinically proven' in relation to the product. Given the strength of this claim and the clear potential for it to mislead and deceive consumers, the CRP considers that its use in advertising should not even be contemplated unless unequivocally supported by robustly designed, published, peer-reviewed clinical trials which have been conducted upon the actual product being advertised or an identical formulation (as a minimum). Even where such evidence is available, the claim must also reflect the weight of all available evidence and not just the specific research being relied upon.<sup>51</sup>

A related point has been made in recent determinations regarding undue emphasis on the weight of scientific evidence in relation to products. For example, in complaint 16-0907, the CRP stated:

When advertisers of therapeutic goods make representations regarding the efficacy of those therapeutic goods, they must ensure that the strength of the evidence is reflected in the strength of the representations. Where evidence is very strong, strong claims may be justified. Where the evidence is of modest quality (but nonetheless supports claims of product efficacy), advertisers must take care not to overstate the quality and nature of the evidence when making

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<sup>48</sup> Ibid [16].

<sup>49</sup> Complaints Resolution Panel Determination, Complaint 2010-06-021.

<sup>50</sup> Ibid [34].

<sup>51</sup> Complaints Resolution Panel, *Highlighted Points from Recent Panel Determinations* (18 August 2008) Therapeutic Goods Advertising Complaints <<http://www.tgacrp.com.au/index.cfm?pageID=21>>.

claims about the product. To do otherwise is likely to mislead the public and breach sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.<sup>52</sup>

The conclusions that can be reached in relation to these decisions are that when assessing the requirements for evidence in relation to advertisements under the TGAC:

- Claims will be assessed against scientific evidence as the default unless explicitly qualified. Great clarity is required when the advertiser is relying on traditional evidence for a claim made about a CAM product to avoid the implication that the evidence relied upon by the advertising is scientific. If the evidence relied upon is traditional evidence rather than scientific evidence then this must be clearly stated.
- If a claim is made that there is scientific evidence or proven effectiveness for a CAM product then the measure of the quality of that evidence is at a high level, that is, a number of high quality published peer reviewed studies involving a substantial number of subjects directed to the specific claims made in the advertisement. The body of all available evidence must be represented by claims, and the evidence must be relevant to the specific representations made.
- If the advertiser does not provide the required quality of evidence, it is likely that a finding of misleading behaviour will be made by the CRP under the terms of the TGAC.

## V RELATIONSHIP BETWEEN LISTING REQUIREMENTS AND TGAC

Regulation 5F of the *Therapeutic Goods Regulations 1990* specifies that applications for pre-approval of advertisements must be made to the Secretary in writing, in a form approved by the Secretary. The form approved by the Secretary for this purpose, includes the following statement:

A claim/indication entered on the ARTG [the Register] will not automatically be approved as an advertising claim. This statement is consistent with Appendix 3 of the TGAC which states that listing or registration of a claim does not automatically mean that the claim may be advertised.<sup>53</sup>

The listing of a CAM product does not require the provision of evidence of verification of indications sought on listing though the sponsor is obliged to have

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<sup>52</sup> Ibid.

<sup>53</sup> Advertising Regulatory Framework, above n 25, 18.

such evidence available on request.<sup>54</sup> This pre-approval process will result in an assessment of the evidence of the level of evidence for a claim or indication by persons not well trained in such assessment.<sup>55</sup> This creates a mismatch between the self-certification for listing and the requirement of pre-approval of evidence for advertising. Initiatives to move away from free-text indications on listing to specific standardised claims on listing may help to alleviate some issues, but sponsors still need to be aware of claims.<sup>56</sup>

## VI REGULATORY FRAMEWORK AND THEORY

This concern has been commented upon in the recent reform process:

A fundamental problem with the current system of pre-approval relates to the treatment of efficacy and performance claims appearing on the ARTG and the treatment of efficacy and performance claims permitted in advertisements. The delegates appointed to approve advertisements assess the suitability of an advertisement in terms of its compliance with the objects of the *TGAC*. The *TGAC* includes the requirement that advertisements contain only claims which the sponsor has already verified. Given that the delegate cannot rely entirely on the ARTG entry to assure themselves that the sponsor has verified all claims that appear in the ARTG, the delegate is placed in a difficult position of having to assess whether or not the sponsor has verified the claims proposed in the application for approval. The *TGA* considers that such an assessment is more appropriately made by those specifically qualified and trained for that purpose and appointed as delegates of the Secretary for that purpose.<sup>57</sup>

Although both processes may involve similar considerations, the *Evidence Guidelines* speak to the nature of evidence to support a particular claim, while the relevant provisions of the *TGAC* speak to a legal concept of misleading conduct. Clearly both documents are generally relevant to each other, but the assessment of misleading conduct is a process that ultimately relies upon the application of legal concepts found in the *Australian Consumer Law* ('*ACL*') – enacted as sch 2 of the *Competition and Consumer Act 2010* (Cth) – in relation to misleading conduct. Key provisions of the *ACL* include s 18, which states that a person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive; and s 29, which states that a person must not, in trade or commerce, in connection with the

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<sup>54</sup> *Therapeutic Goods Act 1989* (Cth) s 28(6).

<sup>55</sup> Above n 25, 19.

<sup>56</sup> Australian Associated Press, 'Sweeping Reforms for CAM Industry: TGA', *Rheumatology Update* (online), 15 February 2013 <<http://www.rheumatologyupdate.com.au/latest-news/sweeping-reforms-for-cam-industry-tga>>.

<sup>57</sup> Advertising Regulatory Framework, above n 25, 18.

supply or possible supply of goods or services or in connection with the promotion by any means of the supply or use of goods or services make certain false or misleading representations.<sup>58</sup> The *Evidence Guidelines*, although not irrelevant to a consideration of what may or may not be misleading conduct, do not have the status of a legislative document that overrides the legal concepts dealt with in the ACL, which are at the basis of this process. Clause 3 of the TGAC confirms that:

All advertisements for therapeutic goods are subject to the *Therapeutic Goods Act 1989* and Therapeutic Goods Regulations, the *Trade Practices Act 1974* [now the *Competition and Consumer Act 2010* (Cth)] and other relevant laws. Compliance with this Code does not exempt advertisements from the application of those laws.

To avoid this dissonance there is a case for the creation of a single body that deals with the listing and registration of therapeutic goods and also provides a pre-approval process for advertising and for the CRP to hear complaints in relation to advertising. If there is a Constitutional limitation on this type of body dealing with therapeutic goods at the Federal level, some form of harmonisation of powers between the states or referral of powers by the states should be considered as occurred in industrial laws under the *Workplace Relations Act 1996* (Cth).

## VII EVIDENCE FOR CLAIMS MADE IN ADVERTISING

To determine the impact of the advertising, under the TGAC the ‘probable impact upon the reasonable person to whom the advertisement is directed’ must be assessed.<sup>59</sup> The TGAC, when dealing with scientific information, suggests that it should be presented in a manner that is accurate, balanced and not misleading.<sup>60</sup> The TGAC is said to be generally consistent with the World Health Organization’s Ethical Criteria for Medicinal Drug Promotion which states:

All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or give rise to undue risks.<sup>61</sup>

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<sup>58</sup> *Competition and Consumer Act 2010* (Cth) sch 2 ss 29(a)-(n).

<sup>59</sup> *Therapeutic Goods Advertising Code 2007* (Cth) cl3(2).

<sup>60</sup> *Ibid* cl 4(4).

<sup>61</sup> World Health Organization, Ethical Criteria for Medicinal Drug Promotion (1988) <[whqlib.doc.who.int/publications/1988/924154239X\\_eng.pdf](http://whqlib.doc.who.int/publications/1988/924154239X_eng.pdf)> 8; *Therapeutic Goods Advertising Code 2007* (Cth) cl 1(2).



The TGAC does not include a definition of the level of scientific evidence required to justify representations, other than the need for approval of certain broadcast media advertisements.<sup>62</sup> After referring to the required documents for submission for approval by the relevant body app 3 states that:

1. Substantiation of therapeutic claims [are] to be provided upon request
2. Substantiation, in line with levels of evidence required to be held by the sponsor at the time of listing or registration, may be required by the advertising services manager
3. Notwithstanding the above, further substantiation may also be requested
4. Listing or registration of a claim does not automatically mean that the claim may be advertised.<sup>63</sup>

The reference to substantiation, in line with levels of evidence required to be held by the sponsor at the time of listing or registration, is a reference to the *Evidence Guidelines*. In this way the verification requirements for indications and claims associated with registration or listing of CAM products is to some extent tied to the advertising of those goods in relation to verification, but there is room for the requirement of further substantiation. Accordingly, the criterion for the determination of the scientific integrity of CAM products for listing and registration is significant in regard to decisions made about advertising.

When seeking to register or list therapeutic goods, there are different levels of evidence required under the Evidence Guidelines, which are intended to deal with general, medium or high level indications and claims.<sup>64</sup> The level of evidence required increases as the category of claim moves from general, the lower level of claim or indication, up to high level evidence, which then permits a higher level of claim or indication. The Evidence Guidelines differentiate between traditional evidence and scientific evidence. If a claim associated with a listing or registration of a therapeutic good relies upon traditional evidence, holding one of the following four sources of evidence provides general level evidence while holding two indicates medium level evidence:

1. TGA-approved Pharmacopoeia.
2. TGA-approved Monograph.

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<sup>62</sup> *Therapeutic Goods Advertising Code 2007* (Cth) cl 3(3), app 3.

<sup>63</sup> *Ibid* app 3.

<sup>64</sup> *Evidence Guidelines*, above n 18, 5-6.

3. Three independent written histories of use in the classical or traditional medical literature.
4. Availability through any country's government public dispensaries for the indication claimed.<sup>65</sup>

General level evidence entitles the use of indications and claims relating to health maintenance, including nutritional support, vitamin or mineral supplementation, and relief of symptoms (not related to a named disease, disorder or condition).<sup>66</sup> Medium level evidence allows indications and claims for: health enhancement; reduction of risk of a disease, disorder or condition; reduction in frequency of a discrete event; aid or assistance in the management of a named symptom, disease, disorder or condition; and relief of symptoms of a named disease, disorder or condition.<sup>67</sup> Another limitation on medium and general level indications and claims is that they may only be made for minor, self-limiting conditions and not serious diseases.<sup>68</sup> All indications and claims based on evidence of traditional use must be worded to the effect that '[t]his (tradition) medicine has been traditionally used for (indication)'.<sup>69</sup> This applies to general and medium level indications and claims. High level indications and claims cannot rely on evidence of traditional use, including indications and claims based on evidence of traditional use for homoeopathic and aromatherapy products.<sup>70</sup>

If the intention is to make indications and claims based upon scientific evidence, sponsors who hold general level evidence can make general level indications and claims. General level evidence includes descriptive studies, case series or reports of relevant expert committees, texts such as *TGA*-approved pharmacopoeias or monographs and other evidence based reference texts. General level indications and claims are: health maintenance, including nutritional support; vitamin or mineral supplementation; and relief of symptoms (not related to a named disease, disorder or condition).

The following kinds of evidence constitute medium level scientific evidence:

- Evidence obtained from well-designed controlled trials without randomisation. In the case of a homoeopathic preparation, evidence from well-designed, controlled homeopathic proving;

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<sup>65</sup> Ibid 6.

<sup>66</sup> Ibid.

<sup>67</sup> Ibid 6-7.

<sup>68</sup> Ibid 7.

<sup>69</sup> Ibid 6.

<sup>70</sup> Ibid.

- Evidence obtained from well-designed analytical studies preferably from more than one centre or research group, including epidemiological cohort and case-control studies; and
- Evidence obtained from multiple time series with or without intervention, including within country and between country population studies.<sup>71</sup>

High level indications and claims are indications or claims that refer to serious diseases or disorders or which relate to: treatment, cure or management of any disease, disorder or condition; prevention of any disease, disorder or condition; and treatment of specific, named vitamin or mineral deficiency diseases.<sup>72</sup>

High level indications and claims require scientific evidence obtained from a systematic review of all relevant randomised, controlled trials without significant variations in the directions and degrees of results or at least one properly designed, randomised controlled (preferably multi-centre) double blind trial.<sup>73</sup> It is preferable to have data from at least two trials independent of each other, but in some cases, one large well-conducted trial may suffice. High level indications and claims can only be made for registerable medicines, not listable medicines.

Although there is reference to the *Evidence Guidelines* in the TGAC, the application of the *Evidence Guidelines* appears not to be discussed by the CRP. In addition, when considering the nature of evidence for any claims made, there is no attempt to apply the various levels of evidence (general, medium and high) and relate that to the types of claims made in the advertisement in relation to whether the indications are general, medium or high. It is significant that general and medium claims such as relief of symptoms (not related to a named disease, disorder or condition) and aid or assistance in the management of a named symptom, disease, disorder or condition can be made if the phrase '[t]his (tradition) medicine has been traditionally used for (indication).' The error made in many advertisements is that there is no proper reference to the fact that the indications rely upon traditional evidence. This would be a breach of the *Evidence Guidelines*. One area where the CRP appears to go beyond the terms of the *Evidence Guidelines* is exemplified in *Kanion Nutrilife Australia Pty Ltd*, where there was reference to the basis of the evidence being traditional use.<sup>74</sup> The CRP commented: 'Evidence that a product has been traditionally used for a

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<sup>71</sup> Ibid 15.

<sup>72</sup> Ibid 7.

<sup>73</sup> Ibid.

<sup>74</sup> Complaints Resolution Panel Determination, Complaint 2011/11/023 to 2011/11/028 (5 April 2012).

particular purpose is not evidence that it is effective for that purpose and cannot support claims of efficacy in advertisements to consumers.’<sup>75</sup>

Although this approach is not excluded by the *TGAC*, it is hard to understand that evidence that is sufficient for listing of a CAM product that permits its entry on the register is not considered to be sufficient for advertising to consumers if the advertisement includes reference to the traditional evidence at the basis of the claim.

### VIII *TGAC* CONNECTION WITH ACL

The decisions made by the CRP are not court decisions. The *TGAC* states that compliance with the *TGAC* does not exempt advertisements from the application of the *TGA* and Regulations, the ACL and other relevant laws. Accordingly, in relation to the *TGAC*, it may be argued that absent a clear exposition of what constitutes ‘misleading conduct’ in the *TGAC*, the primary benchmark should be the ACL.

In determining that question under the ACL, the ‘well-established’ proposition, as recently acknowledged by the High Court in *Google Inc v Australian Competition and Consumer Commission*,<sup>76</sup> is that in assessing the effect of particular conduct on a class of persons (such as consumers), the court must consider whether the ‘ordinary’ or ‘reasonable’ members of that class would be misled or deceived.<sup>77</sup>

However, the ACL is not prescriptive of the evidence required to substantiate claims of misleading conduct. Typically, questions of proof in this area will be resolved by the application of the general principles of the law of evidence and ‘on the balance of probabilities’. Whether a particular representation will be held to be ‘misleading’ is always a complicated question, but more so where the representation is open to a complex or controversial interpretation. While it is likely in such cases that expert evidence will be adduced as to the truth or falsity of the representation, and the impact of the representation on its target audience, the courts have made it clear that the question is ultimately one ‘for the tribunal of fact and ... not ... for any witness to decide’.<sup>78</sup> The treatment of expert evidence by the courts, particularly in the context of the ACL, remains a vexed issue in Australia. This issue is compounded in relation to CAM, where expert witnesses may not possess the scientific pedigrees of their counterparts in orthodox medicine (‘OM’). Equally OM experts may not be familiar

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<sup>75</sup> Ibid [20].

<sup>76</sup> [2013] HCA 1. The case concerned the *Trade Practices Act 1974* (Cth) s 52 which is now ACL s 18.

<sup>77</sup> Ibid [6]-[7].

<sup>78</sup> *Interlego AG v Croner Trading Pty Ltd* (1992) 39 FCR 348, 387.

with the complexities of CAM and, instead, are likely to have specialist knowledge in medical specialties.

As a result of this legal background, in general, considerations of the appropriate evidence for claims made about CAM are applied to CAM based upon an entirely different philosophical and therapeutic paradigm. This has the impact of limiting the promotion of CAM. Based upon some of the provisions described above, there is room for more flexible application of what evidence is available for the justification of CAM claims. It seems that regulators are reticent to apply those measures. It is beyond the scope of this article to explore this issue, but the strictness of the application of the requirement to provide scientific evidence is not universally required in those cases involving misleading and deceptive conduct, whether relating to health issues or otherwise.<sup>79</sup>

### IX ENFORCEMENT OF BREACHES OF TGA

The current regulatory structure under the non-advertising provisions of the TGA, for example, manufacturing or supply of therapeutic goods (sections 19D, 19B and 20A), prescribes offences in relation to therapeutic goods for use in humans. These provisions are subject to a regime of tiered offences involving potential civil and/or criminal liability, infringement notices for strict liability offences and provisions for enforceable undertakings to remedy breaches of regulatory requirements.<sup>80</sup> These provisions do not apply to advertising under the TGA. Under the relevant regulations, advertising breaches attract a maximum penalty of 60 penalty units. This can be compared with much higher penalties for other breaches under the TGA.<sup>81</sup> This situation has resulted in what might be considered regulatory failure based upon the hesitancy of the Commonwealth Director of Public Prosecution ('CDPP') to commence action.

In view of the low penalty levels for advertising breaches, no prosecution has ever been commenced by the [CDPP]. However, if prosecution is commenced and the defendant found guilty of the offence, it would be unlikely for the court to impose the maximum penalties, which in this case are \$6,600 for an individual or \$33,000 for a company. This is because this maximum penalty will only be imposed where the person is a repeat offender and the consequence of the prohibited action was a serious public health risk.

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<sup>79</sup> *Plastec Australia Pty Ltd v Plumbing Solutions and Services Pty Ltd* [2012] FCA 510, 2 [4]; *Olivaylle Pty Ltd v Flottweg AG (No 4)* [2009] 255 ALR 632, 644 [34].

<sup>80</sup> Advertising Regulatory Framework, above n 25, 36.

<sup>81</sup> *Ibid* 37.

In view of the low level of penalty, and in accordance with prosecution policy, the CDPP may refuse to commence proceeding even if there is a strong case. Offence provisions that attract low level penalties may be assessed by the CDPP as being a trivial offence, or the CDPP may consider that there may be other available and effective remedies instead of commencing a prosecution proceeding.<sup>82</sup>

The *TGA* has the power to refer such matters of advertising non-compliance to the CDPP for non-compliance with the *TGAC*.<sup>83</sup> In practice this does not occur, as the low level of penalties means that it is 'not cost-effective for the *TGA* to initiate a formal investigation of an advertising breach with a view to preparing a brief of evidence for consideration of prosecution by the Director of Prosecutions'<sup>84</sup> nor has it ever been so. It is, therefore, seen by the *TGA* as not to be in the public interest to proceed with such actions,<sup>85</sup> even though the *TGA* acknowledges that 'prosecution is currently the only option available where administrative requests fail to achieve compliance.'<sup>86</sup>

Lack of enforcement is, therefore, not related to a lack of appropriate regulations and guidelines. Instead, this is a form of regulatory failure where there is a financial disincentive for the compliance body to commence enforcement proceedings and a lack of regulatory will to enforce regulations. Regulation 9 allows the use of remedies for breach of the *TGAC*, such as withdrawal of an advertisement or publication of a retraction or correction but only on the order of the CRP.<sup>87</sup>

The *Advertising Regulatory Framework* document considers the introduction of a regulatory structure based upon a pyramid of regulatory compliance options suggested by Ayres and Braithwaite:

This model describes a pyramid of regulatory compliance options commencing at the base with educational methodologies and culminating at the peak with the severest monetary and criminal penalties along with removal of privileges conferred by the legislation. The model is widely

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<sup>82</sup> Ibid: Penalty amounts have increased recently and are now \$170 per penalty unit, where here would equal a maximum of \$10,200 for individuals and \$51,000 for corporations.

<sup>83</sup> Therapeutic Goods Act 1989 (Cth) s 42DM.

<sup>84</sup> National Audit Office, Audit Report No.3 2011-12 to Department of Health and Ageing, *Therapeutic Goods Regulation: Complementary Medicines*, 30 August 2011130-1.

<sup>85</sup> Ibid. Before the CDPP may decide to initiate prosecution action for an advertising breach it must consider the allegations against the public interest criteria set out in the 'Prosecution Policy of the Commonwealth': 131.

<sup>86</sup> Ibid.

<sup>87</sup> Advertising Regulatory Framework, above n 25, 37.

supported by a majority of stakeholders as evidenced through references to the regulatory pyramid in submissions from consumers and industry.<sup>88</sup>

The pyramid involves ascending levels of enforcement from ‘persuasion’, ‘warning letter’ and ‘civil penalty’ up to ‘criminal penalty’, ‘licence suspension’ and ‘licence revocation’.<sup>89</sup> This approach has the advantage of proportionality and parsimony in that the option employed is only as intrusive as is necessary to meet the regulatory objectives.<sup>90</sup> This may reduce the cost of enforcement as discussed above, which may not be necessary if the level of enforcement is pitched at lower levels of enforcement and results in a positive outcome for the regulatory authority. However, without enforcement at higher levels (ie civil penalty), it is difficult for lower level actions to persuade breaching organisations to remedy their conduct.

The disadvantages of this type of process relate to whether applying an escalating level of intervention is appropriate in all cases as in some cases – such as issues relevant to the consumption of CAM products – it may be necessary to take immediate action higher up the pyramid scheme.<sup>91</sup> The escalation of remedies up the pyramid may not always assist in a corporate environment where the primary focus is on the prevailing industry culture or competition pressures.<sup>92</sup> The presence of industry competition pressure is likely to be considerable as evidenced by the number of complaints brought by competitors in the ASMI complaint process. Moreover, the relatively small penalties may be outweighed by potential profits made during the time claims are current and promoted.

## X CONCLUSION

The existing regulatory structure for the control of marketing of CAM products under the terms of the TGA and associated regulations is currently under review. The system incorporates some inconsistencies and anomalies discussed in this article including an example of regulatory failure in regard to the level of penalties applied to breaches and the difficulty in applying requirements for evidence for claims and indications for listing and in regard to advertising of products. A rationalization of this process to involve greater integration of those considerations may improve the integrity of the regulatory system. The assessment of the regulatory structure for the advertising of CAM products makes it clear that there is an acknowledgement of the

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<sup>88</sup> Ibid 35.

<sup>89</sup> Arie Freiburg, *The Tools of Regulation* (Federation Press, 2010) 97.

<sup>90</sup> Ibid 268.

<sup>91</sup> Ibid 100.

<sup>92</sup> Ibid.

specific nature of CAM in regard to the provision of evidence as the basis for listing or registration under the *Evidence Guidelines* to allow reference to evidence other than scientific evidence. This is based upon the acceptance that CAM often relies upon traditional evidence to provide evidence of safety and efficacy, and there is currently a lack of scientific evidence for these issues. In regard to advertising of CAM products under the *TGAC*, although there is a connection between the *Evidence Guidelines* and the *TGAC*, there appears to be a reticence to rely upon traditional evidence or other forms of evidence to avoid a finding of misleading and deceptive conduct; although there is adequate provision for that approach under the *TGAC* in relation to the *Evidence Guidelines*. In addition, as the *TGAC* is subject to the terms of the consumer provisions of the *ACL*, any consideration of the issue of what is or is not misleading or deceptive conduct requires a consideration of what would be a breach of the *ACL* when considering advertising under the *TGAC*. As scientific evidence is not required in all cases involving considerations of what is or is not misleading or deceptive conduct under the *ACL* this may allow greater freedom in the application of non-scientific evidence depending on what a court determines in the specific circumstances of the evidence basis for a CAM product, especially if the advertisement acknowledges its reliance upon traditional evidence. More research is required to determine the success and failure of self-regulation to then properly consider the other options which includes more intrusive statutory regulation based upon the specific circumstances of the therapeutic goods industry.