

## Submission to the Review of Medicines and Medical Devices Regulation: Complementary Medicines by Dr Ken Harvey

### Abstract

With respect to the questions raised by the Panel it is my view that there is no suitable overseas “trusted” regulator that could assist the TGA in the assessment of new ingredients.

It is appropriate for Australian medicines policy to include complementary medicines (because of their need for risk-benefit assessment) and not treat them as foods or general items of commerce. Complementary medicines / dietary supplements are primarily taken for their purported therapeutic benefits, unlike foods which may be consumed for taste or hunger regardless of nutritive value, and as such require a medicines regulatory structure.

It is accepted that complementary medicines are relatively low-risk products but that does not mean that they are without risk such as the production of adverse effects and drug interactions. There is a need for approved and consistent Consumer Medicine Information for complementary medicines that provides this important information. Consumers also need to assess the validity of the claims made for complementary medicines and this is best supported by the TGA (using evidence guidelines, post-marketing reviews and the Therapeutic Goods Advertising Code). The current evidence requirements must not be downgraded. The challenge is getting sponsors to comply!

I suggest a small addition to the current regulatory system: make the sponsor add a summary of the evidence they use to self-certify the indications and claims for their product to the ARTG Public Summary document (and their web site) together with appropriate Consumer Medicines Information. This would assist the TGA in conducting targeted and random post-marketing reviews and allow 3rd parties, such as consumer organisations and health activists, to more readily check the information provided.

I accept that the regulatory burden for industry could be reduced by ceasing compulsory pre-vetting of advertisements by delegated industry bodies. The Therapeutic Goods Advertising Code would still need to apply; all complaints would be sent to the TGA and the TGA would need to be given the power to apply timely and meaningful sanctions capable of deterring repeated regulatory violations. In short, option 2 of proposal 3 and 4 in the 2013 “TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public” needs to be implemented!

All AUST L product labels and promotion should be required to show a disclaimer similar to that used by the U.S. FDA.

The latest TGA Half-yearly performance report show around 2000 new listed medicines entered in the ARTG from Jan to Dec 2014. The TGA Complementary Medicine Compliance Review for January to December 2014 shows 190 reviews initiated (9.5% of 2000 new listed medicines; 1.5% of all 12300 listed medicines). Substantial levels of non-compliance were detected (61% of 181 target reviews; 27% of 41 random reviews). It thus seems doubtful if the current TGA post-marketing regime is minimising exposure of consumers to non-compliant complementary medicines.

In my view, the number of post-marketing reviews needs to be at least doubled and (as said before) substantial penalties need to be implemented for regulatory non-compliance. If the fees paid by the complementary medicine industry need to be increased to make this happen, so be it.

# Submission to the Review of Medicines and Medical Devices Regulation: Complementary Medicines by Dr Ken Harvey

## Introduction

I write this submission from the perspective of a public health physician, consumer advocate and educator with a special interest in complementary medicines policy.

The complementary medicine industry assert that their products can increasingly provide consumers and governments with cost-effective health care by both preventing and alleviating disease. For example, omega-3 supplements are claimed to reduce the incidence of cardiovascular disease while St John's wort is said to be a cost-effective remedy for mild or moderate depression. In addition, the industry argues that the current regulatory environment is unnecessarily stringent for what are perceived to be low-risk products.<sup>1</sup>

However, the apparent evidence of benefit from fish oil supplementation has declined as more trials are conducted.<sup>2</sup> Consumption of fatty fish 2-3 times a week, eating less red meat and more vegetables and fruit is currently recommended by public health authorities, not routine supplementation with omega-3 products.<sup>3</sup> In addition, there is concern that the current regulatory environment has allowed fish oil supplements available in Australia and New Zealand to have concentrations of omega-3 fatty acids considerably lower than claimed by labels (and oxidative markers much higher than those recommended).<sup>4</sup>

The Access Economic report cited by CM Australia noted that it is unlikely that all St John's wort products marketed are equally effective (especially as the Australian regulatory system does not assess effectiveness). They suggested that standardisation of St John's wort products (and assessment of efficacy) would be required before these products could be recommended as an alternative to pharmaceutical anti-depressants for mild to moderated depression.

Public health research on dietary supplements has largely concluded that the evidence to support routine supplementation for primary prevention of chronic diseases is inadequate. However, the variability in the composition of dietary supplements makes extrapolating results obtained from controlled clinical trials challenging. Without appropriate regulation to ensure product quality and consistency, the preponderance of evidence collected on dietary supplements may be confounded by unmeasured variability in the supplements used and therefore lack validity.<sup>5</sup> In addition, the value of the substantial expenditure on dietary supplements remains unsubstantiated.

It is accepted that complementary medicines are relatively low-risk products but that does not mean that they are without risk including the production of adverse effects and drug interactions. There is a need for approved and consistent consumer medicine information (CMI) for complementary medicines that provides this important information.

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<sup>1</sup> <http://www.cmaustralia.org.au/Resources/Documents/Technical-Alerts/2015/Complementary%20Medicines%20Australia%20Pre-Budget%20Submission%202015-16.pdf>

<sup>2</sup> <http://www.nps.org.au/medicines/complementary-medicines/for-individuals/fish-oil-supplements/for-individuals/for-heart-health/how-results-have-changed-over-time>

<sup>3</sup> <https://www.nhmrc.gov.au/guidelines-publications/n55>

<sup>4</sup> <http://www.nature.com/srep/2015/150121/srep07928/full/srep07928.html>

<sup>5</sup> <http://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+25602879>

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Companies that market complementary medicines in Australia are legally required to comply with standards set by the Therapeutic Goods Administration (TGA). These standards relate to both the quality of the product and advertising claims. However, the promotional messages promulgated often bear no relation to the minimal or absent evidence underlying them.<sup>6,7</sup> Sponsors of listed complementary medicines self-certify their compliance with TGA requirements. Limited post-market surveillance of complementary products means they can contravene standards with little fear of reprisal. They can de-list a product that has been targeted for review only to relist it once the review has been cancelled. They can ignore the findings of the Therapeutic Goods Advertising Complaint Resolution Panel (CRP). The lack of effective penalties to deter companies from breaching TGA regulations means that it is not surprising that TGA compliance reviews continue to show high levels of regulatory non-compliance.<sup>8</sup>

In short, we currently have a light-touch, toothless, regulatory system that encourages sponsors of complementary medicine to flood the market with products of dubious efficacy, promoted with hype and celebrity endorsement rather than scientific research, and lacking consistent CMI.

The Expert Panel's discussion paper asserts that the TGA regulatory framework provides an important protection to the Australian community by ensuring only safe and effective medicines and medical devices are granted authority to be marketed and/or exported. Yet there is no independent assessment of the effectiveness of complementary medicines by the TGA and no provision of CMI. Without knowing the effectiveness of these products (and their side-effects and interactions) how can consumers and health professionals make "an appropriate balance between risk and benefit"? Meanwhile the industry wants less regulation, not more!

In the light of this introduction, I now address the specific questions posed.

### Questions for consideration

#### ***Theme 1: Duplication of regulatory processes***

**Given the apparent differences in the definition of complementary medicines internationally and the level of pre-market assessment that they undergo, how might Australia determine 'trusted' regulators for the purpose of undertaking assessments of ingredients for use in listed products in Australia?**

It is claimed by industry that many ingredients that are commonly used in complementary medicines in overseas jurisdictions are not available for use in listed medicines in Australia. However, I am not aware of any documentation that validates this assertion. I note that the TGA document, "Substances that may be used in listed medicines in Australia" is 305 pages long and contains around 4,200 substances.<sup>9</sup> Before the question posed by Panel can be properly addressed it would be helpful to have a list of what ingredients the industry felt are missing in Australia and in what jurisdictions (and with what rationale and assessment) they are currently available.

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<sup>6</sup> <https://theconversation.com/krill-oil-marketing-a-case-study-of-australias-broken-regulations-36770>

<sup>7</sup> <https://theconversation.com/still-no-good-evidence-that-most-complementary-medicine-works-29612>

<sup>8</sup> <https://www.tga.gov.au/complementary-medicines-compliance-reviews-outcomes-2014>

<sup>9</sup> <https://www.tga.gov.au/sites/default/files/cm-listed-substances.pdf>

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In addition, the varied results of clinical trials using the same generic ingredient, albeit a complex herbal like St John's wort or a simpler molecule such as glucosamine sulphate, show that it is often not the generic ingredient that is largely responsible for efficacy but rather its specific preparation. Herbal medicines are complex chemical soups whose composition will vary depending on how the herb was cultivated, picked, extracted and standardised. The different salts and preparations of glucosamine also appear to differ in their bioavailability and clinical effect.<sup>10,11</sup>

It's a convenient fiction of the industry (and the TGA) to assert that all that is required is an assessment of the safety and quality of a generic complementary medicine ingredient. Consumers and health professionals need information about the quality, safety and efficacy of a specific standardised and reproducible product. That requires well conducted clinical trials on the specific product in question.

In my view, sites such as the U.S. National Centre for Complementary and Integrative Health, currently provide more helpful information for consumers and health professionals about complementary medicines, including glucosamine<sup>12</sup> and St. John's wort,<sup>13</sup> than the Canadian Natural Health Products Database or other regulators web sites.

My own advice to consumers is to ask their health professional if a specific Australian product is available that has been assessed for efficacy in at least several well-conducted clinical trials.<sup>14</sup>

It is my view (and that of others), that neither the U.S. nor Canada would provide a suitable overseas "trusted" regulator. For example the summary of 2013 article in the Journal of Consumer Affairs titled, "The Regulation of Dietary Supplements within the United States: Flawed Attempts at Mending a Defective Consumer Safety Mechanism" stated:<sup>15</sup>

The use of dietary supplements in the United States has escalated in the past decade, driven by the public's desire to exert control over their health and by the mistaken belief that the safety of dietary supplements is assured by the US Food and Drug Administration (FDA). In fact, the marketing of largely unregulated supplements presents significant risks to public health.

The abstract of a 2015 article in the American Journal of Public Health noted:<sup>16</sup>

Millions of people in the United States consume dietary supplements hoping to maintain or improve their health; however, extensive research has failed to demonstrate the efficacy of numerous supplements in disease prevention. In addition, concerns about the safety of routine and high-dose supplementation have been raised. The Food and Drug Administration regulates dietary supplement quality, safety, and labeling, and the Federal Trade Commission monitors advertisements and marketing; still, vast enforcement

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<sup>10</sup> <http://onlinelibrary.wiley.com/doi/10.1002/art.22728/full>

<sup>11</sup> <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002946.pub2/abstract>

<sup>12</sup> <https://nccih.nih.gov/health/glucosaminechondroitin>

<sup>13</sup> <https://nccih.nih.gov/health/stjohnswort/sjw-and-depression.htm>

<sup>14</sup> <http://www.medreach.com.au/?p=1198>

<sup>15</sup> <http://www.readcube.com/articles/10.1111%2Fjoca.12012>

<sup>16</sup> <http://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+25602879>

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challenges remain, and optimal governmental oversight has not been achieved. If the composition and quality of ingredients cannot be reliably ensured, the validity of research on dietary supplements is questionable. Moreover, the health of the US public is put at risk.

Health Canada has allowed various natural health products to enter the market without requiring rigorous proof of effectiveness. Indeed, there are many remedies and homeopathic preparations currently licensed for sale that do not contain any of the allegedly active ingredient. Health Canada licenses homeopathic preparations purported to prevent polio, measles, and pertussis. <sup>17,18</sup>

### **If a criteria based approach were to be adopted, what criteria should apply in determining whether an overseas regulator is 'trusted' for the purpose of undertaking assessments of ingredients for use in listed products in Australia?**

As mentioned above, I am unaware of any overseas regulator that can be "trusted" to perform an adequate evidenced-based assessment of the quality, safety and efficacy of generic complementary medicine ingredients.

### **Are there aspects of safety or quality that need to be considered in the Australian context? If so, what aspects?**

Information about the safety and efficacy of an ingredient and specific products will change over time and it is important that this is updated in the light of new clinical trials, adverse event reports, etc.

### **How might evidence requirements for listing on the ARTG and for advertising pre-approval of complementary medicines be harmonised? What changes to evidence requirements would be required?**

Many claims ultimately found to be false and misleading by the CRP were pre-approved by delegated authorities because they do not assess the evidence the sponsor has used to justify the claims. Listing requirements and advertising requirements should be harmonised and the sponsor should be asked to provide the evidence supporting both the indications and claims to the TGA (and in the ARTG public summary document) at the time of listing.

This would enable pre-approval of claims (if continued) to be consistent with complaint handling. It would also allow third parties to independently assess the validity of the claims made.

The industry has argued that the evidence supporting their claims is "commercial-in-confidence" and its disclosure would allow competitors to more easily duplicate their product. In my view, this argument lacks merit. If the product was the result of genuine innovation, for example a proprietary standardised herbal extract whose claims were validated by specific clinical trials then the evidence supporting this product could not be extrapolated to other generic preparations of the same herb and innovation is protected.

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<sup>17</sup> <http://www.bcmj.org/council-health-promotion/health-canada-licenses-homeopathic-vaccines> ,

<sup>18</sup> <http://news.nationalpost.com/full-comment/robyn-urback-why-is-health-canada-still-approving-make-believe-homeopathic-vaccines>

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In general, I believe that the 2014 TGA Evidence Guidelines provide a suitable standard for sponsors to self-certify the indications and claims for their product. The exception is the statement on page 28 of the Guideline: <sup>19</sup>

If you are aware that there is conflicting evidence between the history of traditional use and contemporary scientific evidence for your medicine, then it is advisable to include a statement to this effect in any labelling and advertising associated with the medicine, for example: 'this traditional use is not supported by scientific evidence'. This will ensure that the advertised information relating to your medicine is truthful, valid and not misleading (my underlining).

I argue that the word "advisable" must be changed to mandatory". This would eliminate the absurdity of Health Canada's licensing of homeopathic preparations purported to prevent polio, measles, and pertussis and would also provide better guidance to Australian consumers about homeopathic products in the light of the NHMRC Homeopathic Review and Statement on Homeopathy which :<sup>20</sup>

Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective.

The Fact Sheet on Homeopathy and vaccination by the National Centre for Immunisation Research and Surveillance is also relevant: <sup>21</sup>

...no well-designed, well-reported and high quality research can be found that demonstrates the effectiveness of homeopathic "immunisations" for prevention or treatment of vaccine preventable diseases without a significant risk of bias.

### ***Theme 2: Regulatory requirements are not commensurate with risk***

#### **Is the current regulatory regime for complementary medicines in Australia appropriate and commensurate with the risk posed by these products? If not, why not?**

No! Although the risks of complementary medicines are relatively less than OTC or prescription medicines they can produce adverse effects and interact with other medicines. In addition, money spent on complementary medicines of unsubstantiated value wastes resources and may compromise or delay treatment with therapies of proven efficacy.

Consumers and health professionals must make a risk-benefit assessment in determining whether or not to purchase or recommend complementary medicines. Without an assessment of benefit (efficacy) the risk cannot be put in perspective. If there is no (or very doubtful) benefit in taking complementary medicine then even a slight risk becomes an important consideration.

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<sup>19</sup> <https://www.tga.gov.au/publication/evidence-guidelines>

<sup>20</sup> [https://www.nhmrc.gov.au/\\_files\\_nhmrc/publications/attachments/cam02\\_nhmrc\\_statement\\_homeopathy.pdf](https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02_nhmrc_statement_homeopathy.pdf)

<sup>21</sup> <http://www.ncirs.edu.au/immunisation/fact-sheets/homeopathy-vaccination-fact-sheet.pdf>

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Complementary medicines are medicines and decision-making about them requires independent information about their risks and benefits including CMI's. This information is currently not adequately provided by the existing Australian regulatory system.

I accept that pre-market evaluation of low-risk products by the TGA is not appropriate. Rather, I suggest a small (incremental) addition to the current regulatory system: make the sponsor add a summary of the evidence they use to self-certify the indications and claims for their product to the ARTG Public Summary document (and their web site) together with an appropriate CMI. This would facilitate pre-approval of advertising (if continued), assist the TGA in conducting targeted and random post-marketing reviews and also allow 3<sup>rd</sup> parties, such as consumer organisations, to more easily check the claims made.

**Should complementary medicines in Australia be regulated under a separate legislative framework? If yes, what should be the key features of the framework?**

No!

**Should low-risk complementary medicines be regulated as general consumer goods, removing the requirement for listing on the ARTG? If yes, why? If not, why not?**

No! If they were regarded as general consumer goods without TGA oversight and post-marketing surveillance then I believe the public would be placed at much greater risk of from unsubstantiated claims, adulterated and dangerous products.

The industry argues that the ACCC and consumer law exists to provide protection but it is my experience that the ACCC is far too busy with a wide range of consumer issues to focus appropriately on therapeutic goods. While the ACCC has acted on some matters for which the TGA lacked appropriate power, such as Sensaslim<sup>22</sup> and homeopathic immunisation<sup>23</sup> the solution to these problems is to maintain the TGA as the regulator and provide it with similar powers to the ACCC as requested but not yet authorised.<sup>24</sup>

**What criteria should be used to determine whether a complementary medicine should be regulated as a therapeutic good?**

The current definition is perfectly adequate.<sup>25</sup>

**Should certain dietary supplements, such as water soluble vitamins, be regulated as foods or as general consumer goods rather than as therapeutic goods?**

No!

**If not, why not? What is the rationale for continuing to regulate these products as therapeutic goods?**

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<sup>22</sup> <https://theconversation.com/sensaslim-banned-after-medicos-exposure-of-bogus-scientific-claims-4460>

<sup>23</sup> <https://theconversation.com/accc-takes-legal-action-over-homeopathy-claims-12399>

<sup>24</sup> <https://www.tga.gov.au/consultation/consultation-regulation-impact-statement-regulating-advertising-therapeutic-goods-general-public>

<sup>25</sup> <https://www.tga.gov.au/what-are-therapeutic-goods>

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Because the sponsors make therapeutic claims for these products which should be capable of substantiation (but are often not). Consumers need to know the validity of these claims and this is best handled by the TGA (using evidence guidelines and post-marketing reviews) &/or the CRP (using the Therapeutic Goods Advertising Code). In addition, these products can be harmful if taken in excess.

**What criteria should be applied to determine whether a product should continue to be regulated as a therapeutic good?**

Use the current definition and also the TGA's Food-Medicine Interface Guidance tool.<sup>25</sup>

**Should the TGA introduce a modified registration pathway for complementary medicines seeking to make higher level health claims that would allow it to only assess the evidence to support the higher level claims?**

I have some sympathy for this approach.

**Are the current evidence requirements for listed medicines overly onerous?**

No!

**How could the current evidence requirements for listed medicines be altered to reduce the burden on sponsors without reducing consumer confidence that complementary medicines are safe, efficacious and comply with quality standards?**

I do not accept that the current evidence requirements should be altered (with the exception of my comment on page 6). The challenge is getting sponsors to comply!

**Should Australia remove the requirement for manufacturers of low risk products or ingredients to comply with medicinal Good Manufacturing Practice (GMP) standards?**

No!

**If not, why not? What risks do you believe this would create and what evidence is there for this?**

The risks of the U.S. system are clearly described below:<sup>16</sup>

In 2007, the FDA published cGMP guidelines, including requirements for manufacturers to test products to ensure product quality, confirm the absence of some contaminants, verify accuracy of labeling, maintain minimum standards for manufacturing and packing, monitor AE reports, and make all records available for FDA inspection; their purpose was to ensure internal consistency in product quality.

However, these established guidelines do not address the underlying safety of the supplement itself. Moreover, they remain nonbinding on the manufacturer. As a result, manufacturers are reticent to adopt the FDA cGMP guidelines for botanical supplements, which can vary substantially in strength and quality depending on genetic variety and environmental conditions of the plants from which they are derived.



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Despite the cGMP ruling, a 2010 US Government Accountability Office report revealed that an analysis of 40 dietary supplements for the presence of lead, arsenic, mercury, cadmium, or pesticides found trace amounts of 1 or more of these contaminants in 93%.

In 2011, 73% of supplement manufacturers inspected by the FDA failed to adhere to 1 or more regulations. One study reported that 59% of tested botanical supplements contained plant species not listed on the label; additionally, active ingredient substitution was observed among 83% of companies tested.

Poor compliance may be attributed, at least in part, to inadequate enforcement; in 2013, the FDA inspected only 416 supplement manufacturers for cGMP adherence, representing 10% of the estimated 4000 manufacturers covered by cGMP regulations and 2.8% of the 14 995 domestic and international dietary supplement firms registered with the FDA.

Additional limitations of the cGMP guidelines extend even to manufacturers who implement them fully. Because manufacturers set their own standards, the same product from different manufacturers may not be equivalent in composition, strength, or bioavailability.

Manufacturers are not required to confirm the identity of all ingredients supplied to them, and following cGMP guidelines does not guarantee the absence of all contaminants. Moreover, unlike drugs, which are considered adulterated or misbranded if they do not achieve compliance with national standards set by the US Pharmacopoeia and National Formulary, dietary supplement manufacturers may choose whether to be compliant; only 6 brands of dietary supplements are currently verified by the US Pharmacopoeia.

A recent study comparing actual to expected concentrations of vitamin D3 in commercially available brands revealed unacceptable deviations, with pill potency ranging from 9% to 146% of the stated concentration; variability was within acceptable range only for US Pharmacopoeia-verified supplements. Substantial variability in botanical supplement composition and concentrations has also been noted.

### **Should Australia continue to require compulsory pre-vetting of complementary medicines advertised direct-to-consumers**

No. I accept that this is an area where the regulatory burden can be reduced and compulsory pre-vetting by delegated industry bodies could cease.

### **If Australia was to adopt a self-regulatory model or a model which combined risk based regulation with self-regulation (such as the UK) what key elements would need to be in place to ensure that public health and safety was protected, while minimising regulatory burden?**

The Therapeutic Goods Advertising Code <sup>26</sup>would still need to apply; all complaints would be sent to the TGA and, most importantly, the TGA would need to be given the power to apply timely and meaningful sanctions capable of deterring repeated violations of the Code. <sup>24</sup>

In short, option 2 of proposal 3 and 4 in the 2013 “TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public” needs to be implemented!

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<sup>26</sup> <http://www.tgacc.com.au/codeList.cfm?CFID=59078273&CFTOKEN=76952102>

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**Should listed complementary medicines be required to include a disclaimer in all advertising materials and on product labels advising consumers that statements/claims have not been independently assessed by the TGA?**

Yes! In my experience of running a number of workshops on complementary medicine issues for consumers <sup>27</sup> there is NO understanding of the meaning of AUST L compared to AUST R labelled products. I accept that the TGA has added useful information in this regard on their web site (which I use) but the consumers I teach do not look at the TGA web site.

As many submissions have said before all AUST L product labels and promotion should be required to show a disclaimer similar to that used by the U.S. FDA, for example:

This claims made for this product have not been evaluated by Australian health authorities.

However, research has shown that consumers tend to ignore disclaimers, especially when presented in a small font, away from the health claim, and using confusing terminology. <sup>16</sup> It would be sensible to commission advice on how best such information can be presented. <sup>28</sup>

### ***Theme 3: Complex regulatory framework***

**Should sponsors of complementary medicines have to undergo compliance training before being able to list a product on the ARTG?**

This is a matter for industry. In my experience there are companies that know the rules well but repeatedly choose to violate them because of the benefit gained. I suggest that creating penalties that deter such behaviour is more important than compliance training (which is provided by industry associations).

**Is the regulation of complementary medicines transparent enough in terms of informing health consumers about the level of scrutiny that the medicine has undergone? If not, how could it be improved?**

No! See comment on the need for a mandatory disclaimer above.

In addition, timely penalties of a magnitude that deters repeated regulatory violations are crucial.

Using the media to name and shame sponsors that are repeat regulatory violators would also help.

### ***Theme 4: Inadequate deterrents***

**Does the current legislative framework provide sufficient deterrents to prevent sponsors from knowingly listing non-compliant complementary medicines on the ARTG?**

No! The TGA is widely regarded as a toothless trigger!

**If not, what additional measures should be considered?**

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<sup>27</sup> <http://www.medreach.com.au/?p=1198>

<sup>28</sup> <http://communication.org.au/>

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As stated above, the TGA needs to be given the power to apply timely and meaningful sanctions capable of deterring repeated violations of the Code.<sup>24</sup>

In short, option 2 of proposal 3 and 4 in the 2013 “TGA Consultation Regulation Impact Statement: Regulating the advertising of therapeutic goods to the general public” needs to be implemented!

### **Should complementary medicines that are withdrawn from the ARTG require some form of assessment before being able to be re-listed?**

Yes!

The latest TGA Complementary Medicine Compliance Review for January to December 2014<sup>8</sup> showed that 25% of 181 targeted reviews and 32% of 41 random reviews were unable to determine compliance status for reasons such as: the medicine was cancelled by the sponsor; the medicine was cancelled due to non-payment of fees; or the medicine was not yet manufactured. It would be of interest to know the figures for these various reasons. The impression gained is that sponsors evade TGA review by cancelling their products and they then relist making the TGA a subject of ridicule.<sup>29</sup>

A mandatory post-marketing review should be instigated by the TGA in this situation.

### **How effective are the current post-market compliance reviews of complementary medicines in minimising exposure of consumers to non-compliant complementary medicines?**

The latest TGA Half-yearly performance report<sup>30</sup> shows around 2000 new listed medicines entered in the ARTG from Jan to Dec 2014. The TGA Complementary Medicine Compliance Review for January to December 2014<sup>8</sup> shows that there were 190 reviews / investigations initiated (9.5% of 2000 new listed medicines; 1.5% of all 12301 listed medicines). Substantial levels of non-compliance were detected (61% of 181 target reviews; 27% of 41 random reviews).

It seems doubtful if the current TGA post-marketing regime is minimising exposure of consumers to non-compliant complementary medicines.

In my view, the number of post-marketing reviews needs to be at least doubled and (as said before) substantial penalties need to be implemented for regulatory non-compliance. If the fees paid by the complementary medicine industry need to be increased to make this happen, so be it.

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<sup>29</sup> <https://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be>

<sup>30</sup> <https://www.tga.gov.au/sites/default/files/half-yearly-performance-reports-july-december-2014.pdf>