TGA CONSULTATION: THERAPEUTIC GOODS ADVERTISING CODE

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Summary

1. **Minimising subjectivity in the interpretation of the new Code is desirable but easier said than done; much of the Code will remain principle-based.**
2. **Subjectivity of Code complaint determinations will be minimised by adequate and collegiate stakeholder representation on the new TGA complaint system, similar to that contained in the soon-to-be-abolished Complaint Panel.**
3. **We agree with most, but not all, the requirements specified for the new Code. We have also listed important additions. For example:**
    - **Strengthening mandatory warnings on products containing vitamins, minerals and food extracts to support critical public health messages:**

      "Vitamins, minerals and other supplements are NO substitute for a healthy balanced diet. Vitamins, minerals and food extracts are best obtained from food".
    - **Adding mandatory warnings on products with "traditional indications" to inform consumers and protect the TGA (and government) from possible legal action:**

      "This product's traditional claims are based on alternative health practices that are not accepted by most modern medical experts. There is no good scientific evidence that this product works. Also, a tradition of use does not guarantee safety".
4. **Guidelines explaining the new Code will be crucial.**
5. **We reiterate the point made in other submissions; unless the TGA accepts that consumer protection is an equal objective to industry assistance, and gains the will to act, a revised Code and complaint system (including increased penalties and sanctions) will have no more impact than the current dysfunctional system.**
6. **We are concerned that not all the previous suggestions of the Code Council for updating the Code have been noted. In addition, the analysis by the TGA of 48 public submission to the November 2016, Consultation, "The regulatory framework for advertising therapeutic goods" was perfunctory.**
7. **We agree that consumers need access to price information unencumbered by promotional claims.**
8. **Any decision to allow S3 advertising must be based on reliable, high quality evidence of an added benefit to public health for the specific product in question. We are concerned that the advertising of S3 medicines may lead to inappropriate use. Its implementation must be monitored and analysed at the 3-year review of this reform package.**
9. **Given the abolition of the Code Council, and the long delay in implementing previous Council recommendations to update the Code, a timetable to achieve regular revision of the Code must be implemented. Stakeholders should be asked if the Code needs updating at 3-yearly intervals; if the response is affirmative, a public consultation should be held.**
10. **We have documented ongoing problems with advertisements making therapeutic claims for products at the Food-Medicine interface. The focus of the new Code and complaint system, and the legislative changes required, should be broadened to encompass all therapeutic claims, including those made about food, not just therapeutic goods.**

4. Proposed Code changes

4.1. Changes to support effective sanctions and enforcement of advertising requirements

It is proposed that changes be made to the Code include removing, or minimising subjectivity in the interpretation and implementation of the specific advertising provisions set out in the Code.

Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code?

Agreed.

However, this is easier said than done! While some parts of the current Code are objective, for example s.6, "mandatory requirements", much of the Code is principle based and judgement is required to determine if a disputed advertising claim breaches the Code. For example:

> s(4)(1)(b), an advertisement *must*, "contain correct and balanced statements only and claims which the sponsor has already verified" or
>
> s4(2)(c), an advertisement *must not*, "mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions".

This is why the current Complaint Resolution CRP (and Code Council) contains a wide range of stakeholders who are collectively tasked with judging (through the perspective of an average consumer) whether the claim under consideration, and the evidence produced to support it, is in breach of the Code.

As we (and others) have said before, adequate, collegiate, stakeholder representation on the new complaint system is crucial to ensuring subjectivity is minimised when making Code determinations.

Bad decisions, criticised by the Code Council, have been made when TGA officers make decisions in isolation.[1]

In addition, allowing sponsors the flexibility not to use the new permitted indications "word-for-word" will provide additional opportunities for creative interpretation and further difficulties in minimising subjective decisions about Code complaints.

4.2. Core objectives of the new Code

We wish to obtain feedback to support the development of a new Code that is proposed to contain clearer and more specific details of what is and is not permitted in respect of advertisements about therapeutic goods.

The TGA seeks the views of stakeholders on the proposed requirements under the new Code as described above, and any other details or requirements that stakeholders believe should be clearly specified under the new Code.

[1] https://www.tga.gov.au/advert-exempt/advertising-exemption-martin-and-pleasance-restless-legs-relief

Additionally, some stakeholders have called for guidelines to be available for advertisers (see Section 4.4 below).

Do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

1. **Advertisements must comply with the Therapeutic Goods Act 1989, regulations made under this Act, and the (revised) Therapeutic Goods Advertising Code.**

   Agreed.

2. **Advertisements must be truthful, balanced, valid and not misleading. Claims about therapeutic goods must be consistent with the indications (medicine) or intended purpose (medical device) accepted in relation to the ARTG.**

   The term "valid" is not present in the current Code and we are not sure what additional value the word conveys. Its addition needs explanation.

   Medical devices are a particular problem; the brand name advertised often does not appear on the ARTG entry, the "intended purpose" can lack important information that is crucial to the use for which the "device" is promoted, and the advertised use may bear no relation to the "intended purpose".

	For example, the product illustrated, ARTG no: 262312 is included on the ARTG as a Medical Device Class IIa; its intended purpose is an applicator for applying a topical solution designed to treat infected nails (e.g., onychomycosis); yet the ARTG entry does not list the brand name under which the "device" is promoted (making it difficult to find) and it fails to identify the active ingredients, either on the ARTG or in advertisements (which consumers with allergies should be able to find out).

In addition, while there is an attempt to reduce the creativity of complementary medicine sponsors using a limited list of "permitted indications" there is not a similar effort to clean up outrageous "intended purposes" on medical devices.

	For example, ARTG no: 41591 Applicator, ear, single use. Intended purpose: A cone shaped candle that when burnt allows the warmth of the candle to warm the ear canal and loosen the wax and other debris within the canal. The candle flame and geometry creates a gentle vacuum, which through osmosis draws out the debris. Ear candling is associated with real risks, it does not draw out wax and misleading and deceptive claims about its benefits continue despite 30 complaints upheld by the Complaint Resolution Panel (CRP). Product classes that have had repeated Code breaches should be de-listed.

One more example follows.

	There have been 22 previous complaints upheld about FatBlaster FatMagnet products by the CRP. Ten years have elapsed since my colleagues and I first published our concerns in the Medical Journal of Australia about complementary medicines promoted for weight loss".[2] Yet the TGA has failed to conduct a post-marketing review on this class of products, have failed to use sanctions available, such as delisting these products, and have failed to deter numerous new products from entering the marketplace with similar misleading claims.

Which re-emphasises the point made in other submissions; unless the TGA accepts that consumer protection is an equal objective to industry assistance, and gains the will to act, a revised Code and complaint system (including increased penalties and sanctions) will have no more impact than the current dysfunctional system.

What is needed is a change of culture of the TGA to take consumer protection seriously, not just a revised Code and complaint system.

Regardless, the additional provisions in this section are similar to the current Code and are acceptable.

However, we do have comments (also made in other consultations) about **mandatory and applicable information.**

First, we advocate a much stronger statement on the product pack and all promotional material of products containing vitamins, minerals and food extracts. The implicit (and sometimes explicit) message of the supplement industry is that dietary supplements are a substitute for a poor diet.[3,4,5]

The public health message is that there are many misconceptions about the health benefits of supplements, taking them in large amounts can be harmful and, for most people, it's best to get the nutrients our bodies need from eating a variety of healthy, unprocessed foods, not by taking supplements.[6]

Thus, we argue that a mandatory warning on products containing vitamins, minerals and food extracts should support a key public health message.

> "Vitamins, minerals and other supplements are NO substitute for a healthy balanced diet".[7] "Vitamins, minerals and food extracts are best obtained from food".

Second, given the TGA's apparent acceptance of the 144 indications suggested by industry for a Chinese medicine tradition of use, and a further 1000 indications suggested by industry for traditions of use unspecified, we advocate these products must have an accompanying warning / disclaimer on their label and all promotional material:

[2] https://www.ncbi.nlm.nih.gov/pubmed/18205557
[3] https://www.amcal.com.au/vitamins-supplements
[4] http://www.kidssmart.com.au/kids-smart-products/kids-smart-vita-gummies-multivitamin-for-fussy-eaters/
[5] https://vimeo.com/103779600
[6] https://www.betterhealth.vic.gov.au/health/healthyliving/vitamins-common-misconceptions
[7] https://www.eatforhealth.gov.au/guidelines/australian-guide-healthy-eating

"This product's traditional claims are based on alternative health practices that are not accepted by most modern medical experts. There is no good scientific evidence that this product works. Also, a tradition of use does not guarantee safety".

Given increasing concerns about the safety of TCM and other "traditional" products, we believe the government could be liable for legal action from consumers who suffer harm from these products if the TGA continues to allow these products to be marketed without any pre-market evaluation or warning.[8,9]

3. **All claims used in advertisements for therapeutic goods must be substantiated**

Scientific information referred to in advertisements **must be presented accurately, be educationally appropriate** and written in language that can be readily understood by the audience to whom it is directed. Details of the scientific information relied upon must be publicly accessible.

The advertisement must **identify the sponsor of the scientific study** and must also detail if the sponsor of that study has or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted in the advertisement.

Agreed.

In addition, add,

"Scientific information **must reflect the current, totality of knowledge** and not cherry-pick the odd favourable study.".

"Citation of published research used to justify a claim must identify the author(s), article **title, publication, year, volume and page(s) numbers, DOI**[10] **or URL (if available)".**

"The use of the words "**clinically proven**" should be carefully considered. The abolished CRP has been 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 relates.

Given the strength of this claim and the clear potential for it to mislead and deceive consumers, the Panel 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. 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 claims about the product. To do otherwise is likely to mislead the public and breach the Code".[11]

[8] https://theconversation.com/are-traditional-chinese-medicines-safe-and-legal-6373
[9] http://onlinelibrary.wiley.com/doi/10.1111/bcp.13420/full
[10] https://www.doi.org/
[11] http://www.tgacrp.com.au/decision-highlights/

The above requirements also cover **comparative advertising of therapeutic goods**. In addition, the latter must not be disparaging, must be factual, fair, and already substantiated.

Testimonials: we **disagree** that testimonials should be allowed. They are not allowed in the Health Practitioner Regulation National Law (s.133)[12] and if health professionals cannot use them to advertise health services why should advertisers of therapeutic goods?

This prohibition should also extend to celebrity endorsement and recommendations by scientists or healthcare professionals.

We suggest the revised Code should adopt the same stance on prohibition that is used in the United Kingdom:

> "Advertisements to the general public should not contain material which refers to recommendations by scientists or healthcare professionals, or which refers to recommendations by celebrities who, because of their celebrity, could encourage consumption of products".[13]

Certain endorsements by **health-related bodies or organisations** would still be allowed, but subject to requirements to ensure they are not misleading and clearly disclose the relationship with the advertiser and basis for the endorsement.

Agreed.

But, in addition, the disclosure of relationship should also include any financial benefits that are made in return for endorsement.

4. **Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help.**

Agreed; a crucial public health addition.

The current advertisements of most complementary medicines do not list adverse effects and potentially serious drug interactions such as allergic reactions to Echinacea and the interaction of St John's wort with many prescription medicines.

We also argue that:

Sponsorship advertisements should be banned for the same reason we argue the use of celebrities should be banned.

Personal incentives, including free samples, offers of buying one and receiving two, product based contests, etc., should not be offered to pharmacy assistants, other sales personnel, or the general public.[14]

Finally, regarding the questions; do you agree with guidelines to the new Code being developed? How should this guidance be made available to stakeholders?

We agree that guidelines to the Code will be helpful for both industry, complainants and consumers.

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[12] http://www6.austlii.edu.au/cgi-bin/viewdoc/au/legis/nsw/consol_act/hprnl460/s133.html
[13] https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20161004-Edition18-Code-Guidelines-FINAL-V2.pdf
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376398/Blue_Guide.pdf
[14] http://www.medreach.com.au/?p=2263

It should contain explanatory information about the Code,[15] the underpinning legislation,[16] complaint procedures[17], examples of upheld complaints and the sanctions applied (and a link to the complaint register),[18] decision highlights[19] and an online form for submitting complaints.[20]

It should be made available on the TGA web site in a user-friendly format, specifically designed (and tested) to be understood by the different stakeholder audiences targeted: industry health professionals, media and consumers. It should also encourage stakeholders to submit complaints. The U.S. FTC also has some useful examples.[21,22,23]

4.3. The Code Council recommendations

The Council has previously made a number of recommendations to improve the operation of the Code. These included new definitions of prohibited and restricted representation; new restricted representations and suggestions about testimonials and free samples. All had been put on hold pending the outcome of the MMD Review.

At a meeting on August 26, 2016 the Council reviewed previous recommendations made to the TGA over 2007-10 and the 2010 Code revision. The Council also discussed a number of issues relating to the MMD Review recommendations as agenda item 14 & 15. These included:

- Updating the Therapeutic Goods Advertising Code: Specific suggestions;
- Improving the responsiveness and effectiveness of the pre-approval complaint system;
- Improving the responsiveness and effectiveness of the complaint process;
- Dealing more creatively with numerous upheld complaints about claims or indications of the same product;
- Dealing more creatively with recidivist sponsors;
- Providing more specific advice to product sponsors and consumers about common problems;
- TGA list of evaluated registered complementary medicines;
- Unethical advertising claims also contained on ARTG public summary documents;
- ARTG public summary documents for Medical Devices not identifying therapeutic ingredients;
- Approval of restricted representations.

Only a few of these issues have been addressed in this TGA Consultation document.

[15] http://www.tgacc.com.au/FAQ.cfm
[16] http://www.tgacrp.com.au/relevant-legislation/
[17] http://www.tgacrp.com.au/procedures/
[18] http://www.tgacrp.com.au/complaint-register/
[19] http://www.tgacrp.com.au/decision-highlights/
[20] http://www.tgacrp.com.au/complaint-submission-form/
[21] https://www.ftc.gov/news-events/media-resources/truth-advertising
[22] https://www.ftc.gov/news-events/media-resources/truth-advertising/health-claims
[23] https://www.consumer.ftc.gov/articles/0261-dietary-supplements

4.4. Consultation comments

A number of comments were received in response to the November 2016 advertising consultation regarding the proposal to redraft the Code.[24] This TGA Consultation document provides a very limited overview of these comments, suggesting there was:

- Support for the development of a new Code to remove subjectivity by revising the interpretative provisions, particularly in light of the proposed enhanced sanctions and penalties.
- That it is important that any 'simplification' of the process for advertising regulation is not compromised by increased uncertainty around the implementation of the Code itself.
- The Code should clearly and unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising, and that the requirements should be consistently interpreted and applied, as well as being updated on a regular basis
- There should be accompanying guidelines to assist with understanding of the requirements to enable compliance to the Code.

In fact, many other issues were raised as the analysis of these submissions by one of our students showed (Appendix I).

Are stakeholders supportive of including the recommendations in section 4.3 proposed by the Council for incorporation in a new Code?

Do stakeholders support the Code changes proposed in section 4.4 (1 to 3) in the 2016 advertising consultation comments?

No!

We do not believe that the TGA's summary of Council deliberations on a new Code, or the 48 submissions made public, is an accurate representation of the views debated by the Council or the public submissions. See Appendix I.

5. Price Information Code of Practice (PICOP)

The TGA will be considering the mechanism for assisting with price communication and whether the PICOP is appropriate for this purpose and the detailed requirements currently set out in the PICOP.

[24] https://www.tga.gov.au/submissions-received-response-consultation-regulatory-framework-advertising-therapeutic-goods-november-2016

Do you consider that the PICOP should:

- remain in the new Code, or
- be established as a separate legislative instrument under the *Therapeutic Goods Act* 1989, or
- are there other mechanisms for managing compliance with the PICOP?

We agree that consumers need access to price information unencumbered by promotional claims but have no view on how best this should be accomplished.

6. An option for an Advertising Framework for Schedule 3 (pharmacist only) medicines

6.1. Overview

As outlined in Section 3.2 (feedback from the Consultation) there was support from a significant majority of stakeholders for broadening the direct-to-consumer (DTC) advertising of medicines containing these substances.

In most cases, this support was conditional on the expectation that there would be specific requirements for these advertisements to ensure that consumers were aware that pharmacist advice and instructions on use of the medicine were required, and that certain Schedule 3 substances would not be appropriate for DTC advertising.

However, it should be noted that the two consumer representatives (who were in a minority) had reservations about this proposal.

6.2. Product advertising requirements

The following additional requirements are proposed for advertisements for medicines containing Schedule 3 substances:

> **"Your pharmacist *must decide* if this product is suitable for you."**

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the top of the advertisement, for broadcast media this should be the leading statement.

> **"Ask your pharmacist about side effects relevant to you"**

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the bottom of the advertisement, for broadcast media this should be the ending statement.

6.3. Substances unsuitable for inclusion in Appendix H

For some substances, it is acknowledged that direct-to-consumer (DTC) advertising would not be appropriate. It is a proposed that a working group, inclusive of a wide range of stakeholders would assess the existing list of substances included in Schedule 3

6.4. Process for adding a substance to Appendix H

It is proposed that a similar process to re-scheduling, including public consultation, will be followed for consideration of Appendix H inclusion, and in parallel with the scheduling consideration.

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H.

In particular, we would appreciate feedback on

- the specific requirements for advertisements containing Schedule 3 substances
- factors to be considered by the delegate
- restrictions on inclusion in Appendix H
- the proposed process

We believe that advertising of S3 medicines is likely to lead to inappropriate use. This is partly because advertising limits the effectiveness of pharmacists to perform their important gatekeeping function for S3 medicines. It creates a conflict of interest insofar as greater profitability will come from recommending S3 medicines regardless of their appropriateness.

Consumer requests for specific products also interrupts the desired process whereby consumers discuss their needs with pharmacists, who then provide advice about appropriate medication to consumers.[25,26] .

Consumers who demand products are likely to obtain them, even if that product is unsuitable for their needs, by targeting, for example, busy pharmacies where supervision by a pharmacist is 'perfunctory' or from unregulated sources via the internet.[27]

Prohibition of advertising should be the default position for Schedule 3 drugs, with permission for advertising considered on a case by case basis. The decision to allow S3 advertising must be based on reliable, high quality evidence of an added benefit to public health from such advertising for the specific product in question. Its implementation must be monitored and analysed at the 3-year review of this reform package.

7. Next steps

Following review of submissions received in response to this consultation, as foreshadowed in the 2016 advertising consultation, revision of the Code will proceed in consultation with the current Council.

A further round of public consultation on the new draft Code is planned for late 2017 or early 2018. The new Code is expected to be in force before (or at the same time as) other proposed changes to the advertising framework come into effect (July 1, 2018).

The TGA proposes that further revisions to the Code will be consulted publicly in accordance with the established processes for developing and amending legislative instruments (given the abolition of the Code Council).

Given the abolition of the Code Council, and the long delay in implementing the previous Council recommendations to update the Code, a timetable to achieve regular revision of the Code must

[25] https://www.ncbi.nlm.nih.gov/pubmed/16456211
[26] https://www.ncbi.nlm.nih.gov/pubmed/20405595
[27] http://www.bmj.com/content/336/7646/694

be implemented. Stakeholders be asked if the Code needs updating at 3-yearly intervals; if the response is affirmative, a public consultation should be held.

8. Changes to the Therapeutic Goods Act and Regulations needed to implement the above should consider broadening the focus of the Code to encompass all therapeutic claims, including those made about food, not just therapeutic goods.

Increasingly, sponsors of therapeutic goods are reformulating their products as foods to avoid the provisions of the Therapeutic Goods Advertising Code.[28] Such products can be difficult to classify using the Food-Medicine Interface Guidance Tool of the TGA.[29] Complaints sent to the TGA often bounce back and forth between the TGA and State Food Authorities without being resolved. The latter, understandably, are more concerned about food-poisoning in a local restaurant than dealing with misleading therapeutic claims.

In addition, sponsors of foods are adding ingredients about which they are making therapeutic claims. For example, the routine addition of plant sterols to breakfast cereals has recently been approved by FSANZ and the new permission applies exclusively to breakfast cereals sold under the brands Sanitarium Health and Wellbeing or Weet-Bix during an exclusive use period of 15 months.[30,31]

However, the therapeutic claims made about this product appears to breach many of the provisions of the Therapeutic Goods Advertising Code 2015 (Appendix II). Regrettably, there is not a similar Code against which to judge therapeutic claims made for food. There is the Australian Association of National Advertisers (AANA) self-regulatory Food & Beverages Advertising & Marketing Communications Code but it lacks the specific and detailed provisions of the Therapeutic Goods Advertising Code. In addition, in our experience, lodging complaints with the Advertising Standards Bureau has been unrewarding, presumably because of their lack of expertise in evaluating therapeutic claims.

In short, the complaint system for dealing with therapeutic claims about food has exactly the same problems that led the government to streamline and improve the complaint system for advertising therapeutic goods.

The focus of the new Code and complaint system, and the legislative changes required, should be broadened to encompass all therapeutic claims, including those made about food, not just therapeutic goods.

[28] https://theconversation.com/regulations-around-food-medicine-products-fail-to-protect-consumers-14360
[29] https://www.tga.gov.au/food-medicine-interface-guidance-tool-fmigt
[30] http://www.foodstandards.gov.au/code/applications/Documents/A1134%20ExecSummary.pdf
[31] https://www.legislation.gov.au/Details/F2017L00584/Explanatory%20Statement/Text.

Appendix I

Analysis of submissions received in response to the, "TGA Consultation: The regulatory framework for advertising therapeutic goods, November 2016".[32]

Of the 48 public submissions posted, 38% were from industry, 25% from health professional bodies, 13% from media organisations, 10% from consumer organisations or individual consumers, 8% from regulatory agencies, 4% from academics and 2% other (Table 1 below).

Respondents were asked to comment on three models for a new complaint system:

- Model 1, a Commonwealth agency with both the technical expertise and understanding of the regulatory framework (assumed to be the TGA) which would simplify the current multiple complaint handling arrangements with a single process;
- Model 2, outsource complaint handling to an independent non-Government authority, which could operate either with the same statutory powers as the TGA (introducing system duplication) or rely on voluntary undertakings to achieve compliance. However, the non-compliance with the latter would still necessitate referral to the TGA.
- Model 3, a hybrid model with the TGA being the single port of call for complaints and triaging the less serious ones to an external authority. However, as with model 2, non-compliance with the external authority would produce delays while these matters were referred to the TGA.

There were 32 submissions that expressed an opinion about the models proposed. Half of these supported the first model, noting that the TGA had the potential to provide the most efficient and effective system. Health professional bodies provided the most support for this model.

The remaining respondents, especially industry and media organisations, supported Models 2 and 3 in various forms. Some argued that the Advertising Standards Bureau would be a suitable organisation to take over complaint handling, others suggested the Australian Competition and Consumer Commission (ACCC). However, in its own submission, the ACCC noted that specialist regulators are best placed to manage the risks in their area of specialty, given their technical expertise.

Concerns regarding a TGA takeover included the importance of maintaining stakeholder involvement despite the abolition of the CRP, the TGA's record of making inconsistent and/or incorrect decisions in isolation, an ongoing lack of transparency, and their apparent inability to monitor media proactively and effectively. Others were worried that the TGA appeared too closely aligned with industry and lacked a consumer protection culture.

Another recommendation in the consultation was the abolition of pre-approval of the advertising of therapeutic products (which is currently delegated to Industry Associations by the TGA) in favour of a more self-regulatory regime. Pre-approval is currently limited to medicines advertised to the public in "specified media", mainly television, radio and print advertisements, not the internet, and does not include medical devices.

Of thoses who expressed an opinion on this recommendation (n=37), 49% stated outright they believed pre-approval should be maintained, and possibly extended to medical devices and other forms of media. They argued that the current pre-approval process eliminates most non-compliant advertisements, has a relatively short turnaround time (7 days) and remains the only defence

[32] https://www.tga.gov.au/submissions-received-response-consultation-regulatory-framework-advertising-therapeutic-goods-november-2016

between a grossly misleading advertisement in major media and unwitting consumers. In addition, complaint systems and post-marketing reviews take a long time to remove non-compliant advertisements. An additional 36% of submissions had concerns with the implementation of this recommendation. The remaining 15% (primarily industry and media organisations) supported removing pre-approval of advertisements and moving to a more self-regulatory regime.

Finally, the consultation proposed more effective sanctions and penalties for breaching advertising requirements, including civil penalties (substantial fines), injunctions (to restrain a person from contravening advertising requirements) and the power to order compliance, such as the withdrawal of an advertisement and the publication of a retraction.

Of the 39 submissions that commented on sanctions, 79% agreed with the recommendations as outlined in the consultation whilst the remaining 21% had concerns. Despite acknowledging that more effective deterrents were required, some respondents thought the outlined penalties excessive, while others wanted reassurance that the penalties imposed would reflect the severity of the breach. Some suggested that most important change would be the frequency with which penalties were utilised, pointing out that the TGA rarely used sanctions that were already available.

Finally, around half of all submissions (n = 23) commented on the necessity for panel and industry education; of these, 87% agreed with this recommendation. Concerns regarding industry education was primarily that it would be costly and ineffective when compared to the pre-approval system already in place. In addition, some submissions argued there would be no requirement for industry education if the guidelines were sufficiently clear and the regulatory decisions were published in a timely manner.

Table 1: Respondents with submissions publicly available

No	*Submission Name*	*Classification*
1	A Bit Hippy Ltd	Industry
2	Accord Australasia Ltd (Peak body - hygiene, cosmetic and specialty products)	Industry
3	Advertising Standards Bureau	Regulatory
4	Astroglide Pty Ltd	Industry
5	Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEP)	Health Professional Body
6	Australian Association of National Advertisers (Peak Body)	Media
7	Australian Commission on Safety and Quality in Health Care (ACSQHC)	Regulatory
8	Australian Competition and Consumer Commission	Regulatory
9	Australian Dental Association	Health Professional Body
10	Australian Health Practitioner Regulation Agency and National Boards	Regulatory
11	Australian Medical Association	Health Professional Body
12	Australian Self-Medication Industry Ltd	Industry
13	Australian Skeptics Inc	Consumer
14	Australian Skeptics Victorian Branch	Consumer
15	Australian Subscription Television and Radio Association (Peak body)	Media
16	Bandiera, Rhiannon (Flinders Uni)	Academic
17	Boehringer-Ingelheim	Industry

18	Cancer Council Western Australia	Health Professional Body
19	CHOICE (Australian Consumers' Association)	Consumer
20	Commercial Radio Australia (CRA)	Media
21	Communications Council (Peak body for advertising marketing)	Media
22	Complementary Medicines Association	Industry
23	Complementary Medicines Australia (CMA)	Industry
24	Consumer (individual)	Consumer
25	Consumers Health Forum of Australia	Consumer
26	Cosmetic Physicians College of Australasia	Health Professional Body
27	CW Retail Services	Industry
28	Flordis Pty Ltd	Industry
29	Johnson & Johnson	Industry
30	Ken Harvey, Sasha Hall and Tiana Moutafis	Academic
31	Medical Oncology Group of Australia Inc	Health Professional Body
32	Medical Technology Association of Australia Ltd	Industry
33	Medtronic Australasia Pty Ltd	Industry
34	Mylan Australia (Alpha pharm)	Industry
35	Naturopath and Nutritionist	Other
36	Nestle	Industry
37	NewsMediaWorks	Media
38	Outdoor Media Association	Media
39	Pharmaceutical Society of Australia Ltd	Health Professional Body
40	Piper Alderman	Industry
41	Quality Matters Safety Matters Pty Ltd	Industry
42	Royal Australasian College of Physicians	Health Professional Body
43	Sanofi Consumer Healthcare	Industry
44	Swisse Wellness Pty Ltd	Industry
45	The Australasian College of Cosmetic Surgery	Health Professional Body
46	The Pharmacy Guild of Australia	Health Professional Body
47	The Royal Australian & NZ College of Psychiatrists	Health Professional Body
48	The Royal Australian College of General Practitioners	Health Professional Body

Acknowledgment

This analysis was prepared by Ms Eleonora Kay, a final year Monash Biomedicine/Science student, who undertook a Science Intern placement at the School of Public Health and Preventative Medicine, Monash University under the supervision of Dr Ken Harvey.

Appendix II Sanitarium Weet-Bix cholesterol lowering advertisements

Weet-Bix™ Cholesterol Lowering at a glance

- Reduces cholesterol by up to 9%† in four weeks (clinically proven)
- Contains 2 grams of plant sterols per serve (two Weet-Bix Cholesterol Lowering biscuits)
- The Heart Foundation endorses the 2 grams of plant sterols per serve as an effective and easy way to lower cholesterol as part of a healthy diet and lifestyle
- Only food product in Australia to contain 2 grams of plant sterols per serve for 12 months
- Same great taste as the Weet-Bix Australians know and enjoy
- Low in sugar and saturated fat, very high in wholegrain
- Australian owned, Australian manufactured

†2 grams of plant sterols daily lowers cholesterol within 4 weeks as part of a healthy diet low in saturated fat.

https://www.sanitarium.com.au/about/media-room/sanitarium-delivers-australia-first-breakfast-inno

https://www.youtube.com/watch?v=OFIrw-xPPks

Problems with the Sanitarium Weet-Bix cholesterol lowering advertisements

The Heart Foundation Position statement Phytosterol/stanol enriched foods states, "Adult Australians with high absolute risk of CVD benefit from the cholesterol-lowering effect of consuming phytosterols naturally occurring in plant foods and from phytosterol enriched foods". They recommend consumption of 2-3 g of phytosterols per day (along with a healthy diet) ONLY in the high-risk group:[33]

Equally, several meta-analyses by Ras, et al.,[34] Gylling et.al,[35] and others have all looked at the effect of plant sterols in patients with hypercholesterinaemia, not normal people.

It's said that the unpublished trial by Clifton et al., included 46 Australian adults with high cholesterol that were divided into two randomly chosen groups. One group ate 2 Weet-Bix Cholesterol Lowering a day for 4 weeks. The other group at 2 regular Weet-Bix as the placebo control group for the same period. Treatment was then swapped over for the next 4 weeks. It was found that "Weet-Bix Cholesterol Lowering" effectively lowered LDL cholesterol by up to 9% within 4 weeks.

This is a small, unreplicated study and it is assumed, although not reported, that it was funded by Sanatorium. In addition, Dr Peter Clifton has not declared any conflict of interest, for example, is he a paid consultant to Sanatorium? Was he paid for his videos and "advertorial" (attached)?

It is generally not acceptable to use unpublished data to substantiate promotional claims. For example, Medicines Australia Code of Conduct 2015 states (s.1.2.2), "Any information used to support a medical claim or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim. Such substantiating information must not rely solely on 'data on file'". It has been suggested above that the new Code will have similar provisions.

In addition, the CRP has said:[36]

> "The Panel 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 relates. In complaint 2008-02-005, the Panel noted as follows:
>
> The Panel 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 Panel 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.
>
> 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 16-0907, the Panel 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.

[33] https://www.heartfoundation.org.au/images/uploads/main/Heart_Foundation_Position_Statement_-_Phytosterolstanol_enriched_foods_2017.pdf
[34] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4071994/
[35] https://www.ncbi.nlm.nih.gov/pubmed/24468148
[36] http://www.tgacrp.com.au/decision-highlights/

> 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 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."

In conclusion, it can be argued that the Sanitarium promotion (and pack) illustrated has:

- Failed to specify that the "Reduces cholesterol" claim is only relevant to people with elevated blood cholesterol levels;
- Misused the claims, "Reduces cholesterol by up to 9%" and "Clinical proven" as a small unpublished trial does not provide adequate evidence to substantiate this high-level claim for this specific product.
- Misused the National Heart Foundation Position statement by leaving out the caveat that this recommendation applies only to patients with high cardio-vascular risk.
- Misused "professional endorsement" as advertisements should not contain or imply endorsement by individuals who are health professionals.

If such promotion was covered by a Therapeutic Claims Code and Complaint System it would be easy to determine if this promotion was in breach of similar provisions to the current Therapeutic Goods Advertising Code 2015. Without a Therapeutic Claims Code, we are unsure where such concerns should be sent.

DISCOVER THE BREAKFAST CEREAL THAT HELPS FIGHT HIGH CHOLESTEROL

More than 1 in 3 Australian adults have high cholesterol.[1] A number of large, long-term studies clearly show the important role that elevated cholesterol plays in heart health.[2] Lowering cholesterol is recognised by leading health authorities as an important contributor to heart health.[3]

The most effective cholesterol lowering dietary strategies are replacing saturated and trans fats with unsaturated fats and daily intake of plant sterols, as part of a healthy diet.[4] These two strategies account for the majority of the cholesterol lowering effect that is achievable through diet. A daily intake of 2 grams of plant sterols from plant sterol enriched food, as part of a healthy diet and lifestyle, has been proven to lower LDL "bad" cholesterol by up to 9%.[5] Replacing saturated and trans fats with unsaturated fats has the potential to further lower LDL cholesterol by around 6–8%.[4,6]

Professor Peter Clifton

Dr. Peter Clifton is the Professor of Nutrition at the University of South Australia and a general physician. He has over 30 years' experience researching the prevention and treatment of cardiovascular diseases, type 2 diabetes, obesity and other metabolic conditions.

> "OVER THE COURSE OF MY CAREER WE HAVE LEARNT A LOT ABOUT HEART HEALTH AND THE IMPORTANT ROLE THAT DIET AND LIFESTYLE PLAYS. I RECENTLY CONDUCTED A CLINICAL TRIAL IN PARTNERSHIP WITH SANITARIUM HEALTH AND WELLBEING™ AND THEIR NEW BREAKFAST CEREAL PRODUCT WEET-BIX™ CHOLESTEROL LOWERING."

Evidence-based dietary recommendations for the management of cholesterol, including dietary recommendations around plant sterols, are also supported by international authorities. These include the European Society of Cardiology, International Atherosclerosis Society, American Heart Association, Dutch Heart Foundation, Finnish Nutrition Association, Finnish Medical Society, Spanish Atherosclerosis Society and Nutrition Foundation of Italy.

The cholesterol lowering benefits of plant sterols are additive to statins therapy, so the Heart Foundation also recommends that people taking statins can benefit from eating plant sterol enriched foods in addition to statin therapy.[7]

TO LOWER CHOLESTEROL BY UP TO 9%† TAKE TWO A DAY

Dr. Clifton has led an investigation into the efficacy of Weet-Bix™ Cholesterol Lowering at reducing cholesterol. He carried out a randomised controlled clinical trial – the gold standard of scientific studies – of 46 Australian adults with high cholesterol (>5.5mmol/L). Those who ate two Weet-Bix™ Cholesterol Lowering each day for four weeks experienced a significant reduction in their LDL cholesterol levels of up to 9%.

This study also established that by simply eating two Weet-Bix™ Cholesterol Lowering per day some diet quality measures, including daily wholegrain intake, as well as thiamine, riboflavin, niacin and iron, were increased.

Overall, the study supported Weet-Bix™ Cholesterol Lowering as being an effective, easy and nutritious food for people with high cholesterol.

Heart Foundation®

THE HEART FOUNDATION RECOMMENDS THAT PEOPLE WITH ELEVATED LDL CHOLESTEROL EAT 2–3 GRAMS OF PLANT STEROLS EACH DAY FROM PLANT STEROL-ENRICHED FOODS.[7]

NEW

"WEET-BIX™ CHOLESTEROL LOWERING EFFECTIVELY LOWERED LDL CHOLESTEROL BY UP TO 9%† WITHIN 4 WEEKS"

To find out more visit www.sanitarium.com.au/cholesterol-lowering-weetbix-hcp

†Two Weet-Bix™ Cholesterol Lowering daily provide 2g of plant sterols, which is clinically proven to lower LDL cholesterol by up to 9% in 4 weeks as part of a healthy diet low in saturated fat. Weet-Bix™ Cholesterol Lowering may not be suitable for children under 5 years and pregnant or lactating women.

References: 1. Australian Bureau of Statistics. Australian Health Survey: Biomedical Results for Chronic Diseases, 2011–12. 2. Huxley R *et al. Semin Vasc Med* 2002;2(3):315–23. 3. National Vascular Disease Prevention Alliance. Guidelines for the management of Absolute cardiovascular disease risk, 2012. Available at: https://www.heartfoundation.org.au/images/uploads/publications/Absolute-CVD-Risk-Full-Guidelines.pdf. Accessed: 10 May 2017. 4. Clifton P *et al. Aust Fam Physician* 2009;38(6):424–9. 5. Ras R *et al. Br J Nutr* 2014;112:214–9. 6. Mensink *et al. Am J Clin Nutr* 2003;77(5):1146–55. 7. Heart Foundation. Position Statement Phytosterol/stanol enriched foods. Available at: https://www.heartfoundation.org.au/images/uploads/publications/Stanols-QA.pdf. Accessed: 10 May 2017. S&SW. WCL0012MOFPC.

Sanitarium™ health & wellbeing

Weet-Bix™