

Concerns about the Exposure Draft of Therapeutic Goods Amendment (2017 Measures No. 1) Bill and related measures

Summary

We ask the Senate Community Affairs Legislation Committee to:

1. Recommend that the government postpone abandoning the current system of pre-approval of advertisements until the formal 3-year review of the reform package has been completed, thereby enabling data collected to be used as a performance indicator of the advertising reforms (Part 2 of the Bill - Removal of requirement for advertisements to be approved).
2. Change one word of Division 6, section 42DV of the Bill. This states (1), (2), 'the Secretary may, in writing, direct...'. We submit that 'may' should be changed to 'must', otherwise complainants will continue to be frustrated by lack of transparency from the TGA.
3. Question the TGA as to what measures they have devised to involve stakeholders in the new advertising system.
4. Require the TGA to add to their list of permitted indications (see 26BF of the Bill) a requirement that all indications citing traditional evidence must include the following statement (or words to that effect):

"This traditional indication is not in accordance with modern medical knowledge; there is no scientific evidence this product is effective".
5. Recommend that the focus of the new Code and complaint system, and the legislative changes required, be broadened to encompass all therapeutic claims, including those made about food, not just therapeutic goods.

Introduction

This submission is authored by Associate Professor Ken Harvey, School of Public Health & Preventative Medicine, Monash University and Professor John Braithwaite, School of Regulation and Global Governance (RegNet), Australian National University.

It is supported by range of civil society organisations: Choice (Australian Consumers' Association); [REDACTED] Friends of Science in Medicine, Skeptics and Access 2 (The Foundation for Effective Markets and Governance).

It is based on the deliberations of two well-attended seminars that addressed the advertising of therapeutic goods and services (and its regulation). The first was held at Sydney University Health Law Centre in March 2016;¹ the second at Monash Law Chambers in September 2017.² The speakers and audience comprised regulators, lawyers, industry, health professionals and consumers.

The legislation under consideration supports the implementation of additional recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review).³ Several measures will redress long-standing concerns with the advertising of therapeutic goods to consumers and the regulation of complementary medicines. The implementation of these reforms has the potential to make Australia a world leader in the regulation of these matters. However, five concerns have been raised in TGA consultations⁴ and recent seminars.

¹ [Seminar: The Advertising of Therapeutic Good and Services \(and its regulation\), March 17, 2016](#)

² [Seminar: The Advertising of Therapeutic Goods and Services \(and its regulation\), September 8, 2017](#)

³ <https://www.tga.gov.au/media-release/expert-review-medicines-and-medical-devices-regulation>

⁴ <https://www.tga.gov.au/implementation-reforms-public-consultation-forecast>

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Concerns

First, the government accepted a recommendation that the current pre-approval of advertisements in media such as print, radio and television would cease. This was conditional on related reforms also being introduced. These are: increased post-marketing surveillance; a more effective complaint system; increased penalties and sanctions for regulatory violations, and an industry education program. This package of reforms is to commence from July 1, 2018.

We are concerned about abandoning pre-approval of advertisements, at least until the formal 3-year review of the reform package has been completed.⁵ Of 46 published submissions to the TGA consultation on advertising reforms, only 13% supported removal of pre-approval in favour of self-regulation; all came from industry or media organisations.² Of the remainder, 39% argued that pre-approval should remain, 28% noted the importance of managing concerns about this change, while 20% did not comment on this issue.

We acknowledge that the current pre-approval system has limitations; it only applies to “specified media”, mainly television, radio and print advertisements for medicines, not the Internet and not advertisements for medical devices. Responsibility for pre-approval is delegated by TGA to two industry associations (ASMI & CMA); their decisions are not always consistent.

Regardless, the current pre-approval process reviews over 2000 advertisements per year with an average turnaround time of 7 days. Most advertisements reviewed require changes to avoid Code breaches; sometimes wholesale revisions. Pre-approval is the only defence against seriously misleading advertisements on prime-time television or in national newspapers, for example promoting a treatment for cancer.⁶ Complaints and post-marketing reviews take a long time to remove bad advertisements. Prevention is better than cure. In addition, prevention is more economically efficient given that fraudulent therapeutic claims create unnecessary health expenditure.

Furthermore, continuing the pre-approval process until the proposed 3-year formal review would provide a nice performance indicator to judge whether the new advertising system is better than the old one. One would expect the number of pre-approved advertisements requiring revision to fall if other measures in the package are successful.

We ask the Senate Community Affairs Legislation Committee to recommend that the government postpone abandoning the current system of pre-approval of advertisements until the formal 3-year review of the reform package has been completed, thereby enabling data collected to be used as a performance indicator of the advertising reforms (Part 2 of the Bill - Removal of requirement for advertisements to be approved).

Second, we are supportive of the TGA taking over the current convoluted and impotent advertising complaint system. However, there are concerns about the current operation of the TGA which must be addressed. The most important is a lack of transparency in dealing with complaints.

In 2011, an independent panel of consumers, health practitioners and therapeutic goods industry representatives reported on a review to improve the transparency of the TGA.⁷ The Panel noted that consumers and health practitioners have as much interest in therapeutic goods as the industry that produces and markets those goods. It recommended (9) that the TGA improve access and quality of

⁵ <https://www.doctorportal.com.au/mjainsight/2016/38/advertising-reform-watering-down-consumer-protection/>

⁶ <https://www.tga.gov.au/alert/black-and-red-salves-treating-cancer>

⁷ <https://www.tga.gov.au/sites/default/files/review-tga-transparency-1101-final-report.pdf>

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information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints.

Since 2011 the Therapeutic Goods Advertising Complaint Resolution Panel has submitted 541 complaints to the TGA for non-compliance with Panel determinations and other reasons.⁸ Over that time the TGA has only published information about 78 (14%) complaints; 46 that attracted a “Regulation 9 order”,⁹ and 32 complaints where compliance was achieved following “TGA intervention”.¹⁰ Numerous additional complaints, sent direct to the TGA, have never been reported upon. In short, the increased transparency recommended in 2011 has yet to be achieved.

Division 6, section 42DV of the Bill states (1), (2), ‘the Secretary may, in writing, direct...’ and (6) ‘As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department’s website’. We submit that the word ‘may’ (above) should be changed to ‘must’, otherwise complainants will continue to be frustrated by lack of transparency from the TGA.

Third, additional concerns about the TGA include the need for continued stakeholder involvement (currently provided by the Complaint Resolution Panel and Code Council which are to be abolished) and a culture better attuned to consumer protection, not just industry assistance. The 2011 Transparency Review considered that the TGA should move away from the conservative approach that has characterised its actions in the past and recognise that it has a duty to collaborate with stakeholders to create a culture in which the community has confidence in the therapeutic goods the TGA regulates. Many suggestions made by consumer and health professional organisations in recent TGA consultations appear to have been ignored while those from industry have been taken up. It has been suggested that seconding a senior manager from the ACCC Enforcement Division to the new TGA Advertising Unit might assist the cultural change required.

We ask the Senate Community Affairs Legislation Committee to question the TGA as to what measures they have devised to reassure stakeholders about these matters.

Fourth, with respect to the regulation of complementary medicines, the government has accepted a package of recommendations designed to reduce non-evidence-based claims and stimulate innovation. This package has three components: limiting product claims that can be made without pre-approval by the TGA (the permitted indication list); a new assessment pathway whereby sponsors who have clinical trial evidence to justify an intermediate-level claim can submit this to the TGA to get their claim approved, and a period of data protection for sponsors who provide data for an approved evidence-based claim or a new ingredient.¹¹

We are concerned about the TGA’s proposed permitted indication list.¹² The current list contains 1,345 draft permitted indications submitted by industry; many seem to lack evidence to back them (evidence that a sponsor must hold albeit not usually assessed by the TGA). Recommendation 44 of the Review advocated that a prominent disclaimer should be applied to all advertising material relating to Listed complementary medicines, noting that efficacy claims for these products have not been independently

⁸ <http://www.tgacrp.com.au/> (Complaint summary documents)

⁹ <https://www.tga.gov.au/decisions-relation-complaints-about-advertisements-sorted-date>

¹⁰ <https://www.tga.gov.au/ws-rec2sec-index>

¹¹ <https://theconversation.com/which-supplements-work-new-labels-may-help-separate-the-wheat-from-the-chaff-73189>

¹² <https://theconversation.com/new-complementary-medicine-health-claims-lack-evidence-so-why-are-they-even-on-the-table-80896>

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assessed. This was opposed by industry and rejected by the current government, presumably because of industry lobbying and TGA acquiescence.

In addition, the TGA's proposed list contains around 1000 indications for "traditional medicines" such as Homeopathic products, Traditional Chinese Medicines, Ayurveda, etc. Australia is a multicultural society, and it is appropriate we respect and have some knowledge of alternative medical traditions. In addition, some observations made in these traditions have led to valuable, efficacious medicines. A recent example is Artemisinin derivatives, used for treating resistant strains of malaria, isolated from sweet wormwood (*Artemisia annua*) used in traditional Chinese medicine since the 4th century.

However, scientific investigation has not substantiated many other aspects of these traditions, such as the homeopathic principles of "like cures like" and traditional Chinese medicine concepts of meridians through which the life-energy known as "qi" flows. In addition, we cannot assume traditional medicines are safe, as emerging data shows that adulteration, adverse reactions and drug interactions are common.^{13,14}

For consumers to make an informed choice about these medicines we submit that a claim based on "traditional use" should always have a disclaimer along the lines of what the US Federal Trade Commission uses for homeopathic products.¹⁵ For example,

"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".

We are concerned that the current list of permitted indications, without disclaimers for traditional medicines, implies government endorsement of pseudoscience. Worse, it will encourage consumers to purchase often ineffective and sometimes dangerous products. It is also not in accord with the Objects of the Therapeutic Goods Act 1989 (s.4(1)(a)):

"to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods..." (our emphasis)¹⁶

The TGA have recently approved the advertising of several products making "traditional" claims where scientific evidence is lacking.¹⁷ One explanation for these decisions, including the TGA's acceptance of around 1000 "Traditional" permitted indications (submitted by industry) without insisting on a clarifying statement, is "regulatory capture".

We are concerned that 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 promoted and sold without pre-market evaluation or an appropriate warning.

We ask the Senate Community Affairs Legislation Committee to require the TGA to add to their list of permitted indications a requirement that all indications citing traditional evidence include the following statement (or words to that effect):

"This traditional indication is not in accordance with modern medical knowledge; there is no scientific evidence this product is effective".

¹³ <https://www.ncbi.nlm.nih.gov/pubmed/22374080>

¹⁴ <http://onlinelibrary.wiley.com/doi/10.1111/bcp.13420/full>

¹⁵ https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/homeopathic_drugs_frn_12-13-2016.pdf

¹⁶ http://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/tga1989191/s4.html

¹⁷ [TGA provides complementary medicine industry with "Get Out of Jail Free card"](#)

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Fifth, increasingly, sponsors of therapeutic goods are reformulating their products as foods to avoid the provisions of the Therapeutic Goods Advertising Code.¹⁸ Such products can be difficult to classify using the Food-Medicine Interface Guidance Tool of the TGA.¹⁹ 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.^{20,21}

However, the therapeutic claims made about this product appears to breach many of the provisions of the Therapeutic Goods Advertising Code 2015. 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.

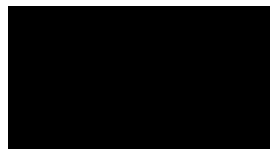
In short, the complaint system for dealing with therapeutic claims about food has the same problems that led the government to streamline and improve the complaint system for advertising therapeutic goods.

We ask the Senate Community Affairs Legislation Committee to recommend that the focus of the new Code and complaint system, and the legislative changes required, be broadened to encompass all therapeutic claims, including those made about food, not just therapeutic goods.

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Friends of
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¹⁸ <https://theconversation.com/regulations-around-food-medicine-products-fail-to-protect-consumers-14360>

¹⁹ <https://www.tga.gov.au/food-medicine-interface-guidance-tool-fmig>

²⁰ <http://www.foodstandards.gov.au/code/applications/Documents/A1134%20ExecSummary.pdf>

²¹ <https://www.legislation.gov.au/Details/F2017L00584/Explanatory%20Statement/Text>.