TGA CONSULTATION: PROPOSED THERAPEUTIC GOODS ADVERTISING CODE GUIDANCE

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Summary

Previous submissions to TGA consultations have noted that many recommendations made by civil society had been ignored.

Most have still been ignored in this draft Guidance document.

Accordingly, we see little point in responding in detail to this consultation.

Instead, we wish to highlight the key point repeatedly made in previous consultations.

> **'No amount of "guidance" will improve the current dysfunctional regulatory system for complementary medicines and advertising unless the TGA accepts that consumer protection is an equal objective to industry assistance and gains the will to act against companies that consistently break the law.'**

Over the 18-year life of the Complaint Resolution Panel (CRP), the TGA received 755 complaints referred for non-compliance or because repeated upheld complaints about the same matter required regulatory action. The TGA have published the outcome of only 80 (11%) of these referrals.

The TGA have failed to remove medical devices such as BICOM despite expert opinion pointing out that it does not fit the criteria of a legitimate biofeedback device and the claims made are preposterous.

The TGA have failed to act on companies that consistently break the law, nor have they targeted for post-marketing review products of public health concern, such as weight loss products, that have had many upheld complaints.

The TGA's new complaint system is much less transparent that the CRP system it replaced. While this is convenient for industry and the TGA, it is appalling consumer protection.

The critique by Commissioner Hayes of the financial services industry and their regulators is equally applicable to the complementary medicine industry and the Therapeutic Goods Administration. A failure to enforce the law undermines the authority of the regulator whose fundamental responsibility is to do just that. It also encourages others to break the law, leading to a race to the bottom.

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Background

This consultation[1] noted, "Many stakeholders who made submissions to the April 2018 consultation[2] on the draft Therapeutic Goods Advertising Code 2018 (the Code) called for further consultation on the Code guideline". Typically, these submissions have yet to be published by the TGA.

Regardless, our previous submissions noted that many previous Code recommendations made by civil society had been ignored (Appendix I).[3,4,5] Most have still been ignored in the Guidance document.

Indeed, an analysis of published submissions to many TGA consultations shows that even majority views are routinely ignored by the TGA (soon to be published). Accordingly, we see little point in responding in detail to this consultation. Instead, we wish to highlight a point repeatedly made in previous consultations.

Our key point

No amount of "guidance" will improve the current dysfunctional regulatory system for complementary medicines and advertising unless the TGA accepts that consumer protection is an equal objective to industry assistance and gains the will to act against companies that consistently break the law.

Past failure of TGA to act.

At APHC 2018, my colleague Malcom Vickers presented his research on the work of the Complaint Resolution Panel (CRP), over its life from 1999-2018:[6]

- Pharmacare were the worst therapeutic goods company with a history of 104 justified CRP complaints. Swisse and Blackmores were the next worse with 33 and 32 justified complaints respectively. Pharmacare complaints were referred to the TGA 21 times but the TGA has only published the outcomes of 2 of these referrals.
- Pharmacare are responsible for such products as "Horney Goat Weed for Him" and "...Her", "Kids Smart Vita-Gummies", and the "FatBlaster" range of products including "FatBlaster Magnet".
- Pharmacare's behaviour of breaking the law has not changed significantly over 18 years. They achieved a high of 12 justified complaints in 2003 and have not had a year with less than 2 justified complaints since records began in 1999.
- Over the life of the CRP, the TGA received 755 referrals from the CRP for non-compliance with CRP requests, or because repeated upheld complaints about the same matter required regulatory action.
- The TGA have published the outcome of only 80 (11%) of these referrals.

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[1] https://www.tga.gov.au/consultation/consultation-proposed-therapeutic-goods-advertising-code-guidance

[2] https://www.tga.gov.au/consultation/consultation-draft-therapeutic-goods-advertising-code-2018-and-associated-guidelines

[3] http://www.medreach.com.au/wp-content/uploads/2017/10/Consultation-Submission-The-Therapeutic-Goods-Advertising-Code-Harvey-Ranaweera-Kay-FSM-Final.pdf

[4] http://www.medreach.com.au/wp-content/uploads/2017/05/TGA-Consultation-Submission-The-regulatory-framework-for-advertising-therapeutic-goods-Harvey-Hall-Moutafis-Final.pdf

[5] http://www.medreach.com.au/wp-content/uploads/2018/06/TGA-Consultation-Submission-Draft-Therapeutic-Goods-Advertising-Code-2018-Harvey-Vickers-FSM-FINAL_V2.pdf

[6] http://www.medreach.com.au/?p=2804

- Friends of Science in Medicine have noted that the TGA have failed to remove medical devices, such as the BICOM device, despite expert opinion pointing out that it does not fit the criteria of a legitimate biofeedback device and the claims made are preposterous.
- In short, the TGA have failed to act on companies that consistently break the law, nor have they targeted products of public health concern, such as weight loss products, that have had numerous upheld complaints.

Current failure of the TGA to act

From 1 July 2018 the TGA took over the therapeutic goods complaint system from the CRP There are now numerous complaint "outcomes" on the TGA web site.[7] Most appear to have been assessed by the TGA as "low priority" and closed with a "Compliance notice sent with educational material". This priority was awarded despite complaints having had numerous previously upheld determinations by the CRP to which the sponsor failed to respond.

The TGA's new complaint system provides much less transparency that the CRP system it replaced. For the numerous complaints regarded as "low priority" by the TGA there is no follow-up to see if compliance has been achieved by the "educational letter". From complaints we have submitted, compliance has usually not resulted from the TGA's letter.

Even "critical priority" complaints, which the TGA reported as "action taken - Formal contact requiring immediate action, warned – Compliance achieved without formal action – closed", have had their promotion continued.[8]

In addition, unlike the old CRP system, the new TGA system provides no search facilities. Consumers concerned that they may have purchased a product with upheld complaints, or consumers who wish to check the status of a product currently being advertised cannot do so, even if the product has been the subject of a "critical" complaint. While this is convenient for industry and the TGA, it is appalling consumer protection.

Recommendations:

- The TGA must follow up "educational letters" and other interventions and report if compliance has been achieved.
- The product name and advertiser of all complaints judged to breach of the Therapeutic Goods Advertising Code must be reported and be searchable on the TGA web site.
- The TGA must report the outcome for the large numbers of previous complaints sent by the CRP to the TGA because regulatory action was needed.

Conclusion:

The critique by Commissioner Hayes of the financial services industry and their regulators is equally applicable to the complementary medicine industry and the Therapeutic Goods Administration.

- Corporations misled and deceived consumers, they provided products that were not fit for purpose, they did not act in consumers best interests, they broke the law.

[7] https://compliance.tga.gov.au/advertising-complaints-outcomes/

[8] http://www.medreach.com.au/?p=2731

- When misconduct was revealed, it either went unpunished or the consequences did not meet the seriousness of what had been done.
- Too often, entities were treated in ways that allowed them to think that they, not the regulators, will decide when and how the law will be obeyed or the consequences of a breach remedied.
- Essentially, a failure to enforce the law undermines the authority of the regulator whose fundamental responsibility is to do just that. It also encourages others to break the law leading to a race to the bottom.

Why has the TGA not acted? Are they captured by industry, lazy, incompetent, or all the above?

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