


Agenda item 8: Choice Feedback

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TGACC Meeting, Sydney 20 Feb 2020



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Why regulate advertising of therapeutic goods?



- Consumer protection.
- Enhance health outcomes.
- Promote quality use.
- Encourage responsible advertising.
- Provide a level playing field for businesses.
- Support consumer confidence and trust in the regulator.

<https://www.tga.gov.au/why-and-how-advertising-therapeutic-goods-regulated>

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CHOICE Role of the TGACC

- Provide input to policies relating to the administration of the Therapeutic Goods Advertising Code.
- Provide a forum for engagement on emerging issues with respect to therapeutic goods advertising.
- Assist with shaping TGA reporting activities with respect to advertising compliance.
- Provide input on the development of education and compliance priorities to address non-compliance of advertising for categories of therapeutic goods.

<https://www.tga.gov.au/committee/therapeutic-goods-advertising-consultative-committee-tgacc>

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CHOICE Problems with TGACC meetings

- Mainly talked at by TGA staff; very limited discussion of problems.
- Not a forum that makes use of member's experience and expertise.
- Voluminous agenda papers arrive late leaving little time for detailed consideration.
- Choice agenda suggestions (sent on 22 January 2020) not incorporated; told to, 'circulate it yourself'.

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Choice suggested agenda items not dealt with

- Concerns about complaint classification.
- Failure of Regulatory Obligations letters to achieve compliance.
- The significant backlog of unresolved complaints
- Common and ongoing advertising Code breaches.
- Outcome of many TGA Reviews, Consultations & Education Campaigns.
- Suggested additions / changes to the Therapeutic Goods Advertising Code and Regulations.


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Concerns about complaint classification: examples



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Obligations letters do not achieve compliance

Email: [REDACTED]

Dear Sir/Madam,

YOUR LEGAL OBLIGATIONS WHEN ADVERTISING THERAPEUTIC GOODS

The Therapeutic Goods Administration (TGA) is writing to remind you of your legal obligations when advertising therapeutic goods, such as medicines and medical devices. Advertisements for therapeutic goods must comply with the *Therapeutic Goods Act 1989* (the Act), Therapeutic Goods Regulations 1990 (the Regulations) and the Therapeutic Goods Advertising Code 2015 (the Code).¹ Your advertising has come to the TGA's attention through a complaint.

The TGA will not be pursuing this complaint any further at this time. However, your advertising may be monitored for compliance or under an assurance review, and any future complaints will be considered having regard to this correspondence.

The TGA is notifying you of this complaint so you can ensure your advertising is compliant with the law.

Further information on the new complaints framework and other reforms to the advertising framework for therapeutic goods is available from <https://www.tga.gov.au/reforms-therapeutic-goods-advertising-framework>.

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Backlog of unresolved complaints

- 5 July 2018, [Pharmacare Laboratories Ease-a-cold products](#), AL-B81GN1V3/2018
- 6 July 2018, [Pharmacare Laboratories Promensil Menopause products](#), AC-4I7BPN1V/2018.
- 6 July 2018, [Pharmacare Laboratories FatBlaster FatMagnet products](#), AC-GBKDH2XG/2018
- 7 July 2018, [Pharmacare Laboratories Nature's Way Magnesium Products](#), AC-GOZU449N/2018
- 9 July 2018, [Pharmacare Laboratories Sambucol Products](#), AC-FR55H9ST/2018
- 12 July 2018, [Pretorius, Bioglan, Healthy Care Homeopathic Products](#), AC-9NXC9UV6/2018
- 15 July 2018, [Au Remedial, Pain®Gone and Pain®Gone Plus](#), AC-KD45638R/2018
- 7 August 2018, [Multiple Hangover products: Plus Daily Ltd Recoverthol, Clever Health Rejoove, Body Armour Pty Ltd Hangover Relief, D & X Pty Ltd Hey! King Premium Hangover Relief](#); AC-JY0FXQ3S/2018
- Etc.

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Common, ongoing Code breaches

- Failure to keep up to date with new studies that invalidate older ones, e.g.
 - Omega-3 for 'heart health',
 - Glucosamine for osteoarthritis,
 - Ginkgo biloba for mental enhancement.
- Failure to recognize new restricted representations in permitted indications, e.g.
 - Benign Prostatic Hypertrophy (BPH) and Saw Palmetto.

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Common, ongoing Code breaches

- Failure to add information required for therapeutic goods that are not available for physical examination before purchase
 - especially amazon.com.au.
- Failure to follow TGA evidence guidelines (pg. 22) when there is conflicting evidence between the history of traditional use and contemporary scientific evidence, e.g.
 - Homeopathic products
 - Bach Rescue Remedies .

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CHOICE Outcome of TGA Reviews, Education Campaigns, etc.

- [Oral probiotics indicated for vaginal conditions](#) (October 2016)
- [Targeted project: Macular degeneration](#) (June 2017)
- [Review of listed medicines with traditional indications](#) (July 2018)
- [Review of listed gummy supplements](#) (July 2018)
- [TGA cracking down on non-compliant advertising of bioresonance and similar devices](#) (August 2019)
- [Consultation: Proposed clarification that goods are therapeutic goods - goods containing folate substances in certain circumstances](#) (October 2019)
- [Proposed clarification that certain sports supplements are therapeutic goods](#) (October 2019)

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CHOICE Suggested changes to the Code and Regulations

- Section 12 (*What must advertisements contain— therapeutic goods that are not available for physical examination before purchase*): Add
 - s.12(3)(g) the ARTG number prominently displayed
 - s.12(4)(g) the ARTG number prominently displayed
 - s.12(5)(g) the ARTG number prominently displayed
- Section 16 (Endorsements): Replace with
 - ‘Advertising must not include endorsements about a product, service or businesses’
- Section 17 (Testimonials): Replace with
 - Replace (1-3) with ‘Advertising must not include testimonials about a product, service or businesses.’
- Etc.

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CHOICE In conclusion - has the TGA regulatory system achieved:

- Consumer protection?
- Enhanced health outcomes?
- Quality use of medicines?
- Responsible advertising?
- A level playing field for businesses?
- Consumer confidence and trust in the regulator?

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CHOICE The TGA's first consumer survey shows it has not

June - July 2018

It employed a random population-based sample (Panel) and an Opt-in sample sourced through known TGA contacts, networks and consumer stakeholders.

Agreed with the statement: Complementary medicines are	Panel (n=1045)	Opt-in (n=684)
Appropriately regulated	32%	15%
Monitored by government for safety	42%	18%
Manufactured to a high standard	38%	21%
Trusted	38%	24%
Safe	39%	26%

<https://www.tga.gov.au/tga-consumer-survey-2018>

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