




Brain food?



<https://www.youtube.com/watch?v=3zY164VtwBg&t=24s>


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Souvenaid: Concerns

- Self-declared food for special medical purposes (treatment of mild Alzheimer’s disease).
- If a medicine, the promotion would breach the Therapeutic Goods Advertising Code:
 - Advertising for serious disease prohibited unless pre-approved.
 - Endorsement of products by health-care professionals prohibited.
 - Scientific studies cited are of dubious clinical significance and not in accord with guidelines on “clinically proven”.
- Sold over the Internet without medical consultation. 8

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Souvenaid: Complaint outcome

- From NSW Food Authority (14 months after initial complaint submitted):
 - as Souvenaid was determined to be a food, it was not subject to the requirements of the *Therapeutic Goods Advertising Code 2007* or associated *Guidelines*.
 - In response to the Authority’s investigation the supplier agreed to amend a number of the claims in their advertising material.
 - Your concern about the ability to purchase this product online was noted, however Clause 10(1)(a) of Standard 2.9.5 only requires a statement to the effect that the food must be used under medical supervision.

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Sports foods and drinks: Controversial



Standard 2.62 includes sports drinks

Standard 2.94 sports food

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Choice Shonky Award 2017




<https://www.choice.com.au/shonky-awards/hall-of-shame/shonkys-2017/vitamin-gummies>

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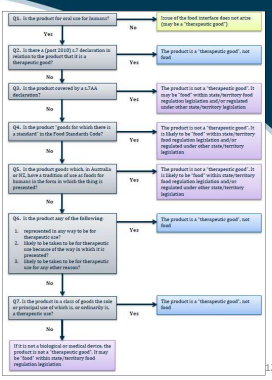


Kids gummies: food or medicine?



No ARTG ID

ARTG ID: 280983



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Problems with kids sugar coated gummies

- Some are regulated as foods, others as medicines.
- If a food, the sugar content must be declared; if a medicine, only, “contains sugar” is required.
- State poison information centres report increasing calls from parents worried their children have swallowed numerous gummies thinking they were lollies.
- Given the high incidence of dental caries in Australian children should these products be allowed?
- Who is responsible? FSANZ or the TGA?

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Ayurda Livgood

No ARTG number

A natural formulation that helps the liver expel the build up of toxins from the liver which accumulate from a diet that includes fried & highly processed foods.

“Useful in the treatment of: Acne, Gastritis, Gout, Liver disorders, Psoriasis.”

Ingredients:
Picrorrhiza kurroa, Andrographis paniculata, Aloe barbadensis, Phyllanthus fraternus, & Boerhaavia diffusa

are used in Ayurveda to protect the liver from the impact of overindulgence.

Quantity - 60 capsules

Price: \$36.00 inc GST

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graph TD
    Q1[Q1. Is the product for use for humans?] -- No --> R1[The product is not a 'therapeutic good' - not listed]
    Q1 -- Yes --> Q2[Q2. Is there a 'good reason' for declaration to be made in the product label as a 'therapeutic good'?]
    Q2 -- No --> R2[The product is not a 'therapeutic good' - not listed]
    Q2 -- Yes --> Q3[Q3. Is the product covered by a TGA 'therapeutic good' determination?]
    Q3 -- No --> R3[The product is not a 'therapeutic good' - not listed]
    Q3 -- Yes --> Q4[Q4. Is the product 'made for' or 'intended for' use as a 'therapeutic good' in the 'therapeutic good' determination?]
    Q4 -- No --> R4[The product is not a 'therapeutic good' - not listed]
    Q4 -- Yes --> Q5[Q5. Is the product 'made for' or 'intended for' use as a 'therapeutic good' in the 'therapeutic good' determination?]
    Q5 -- No --> R5[The product is not a 'therapeutic good' - not listed]
    Q5 -- Yes --> Q6[Q6. Is the product 'made for' or 'intended for' use as a 'therapeutic good' in the 'therapeutic good' determination?]
    Q6 -- No --> R6[The product is not a 'therapeutic good' - not listed]
    Q6 -- Yes --> Q7[Q7. Is the product 'made for' or 'intended for' use as a 'therapeutic good' in the 'therapeutic good' determination?]
    Q7 -- No --> R7[The product is not a 'therapeutic good' - not listed]
    Q7 -- Yes --> R8[The product is a 'therapeutic good' - listed]
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Complaint sent to CRP, 20 Nov 2017

No ARTG number

- This product is being sold, apparently as a food (labelled as a dietary supplement), but is making therapeutic claims.
- It's not listed on the ARTG (a breach of the *Therapeutic Goods Act 1989* Section 22 (5)) .
- In addition, the claims made breach many sections of the *Therapeutic Goods Advertising Code 1995*, including section 4(2)b, 4(2)c and 5(2).

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Complaint 2017/12/002 Ayurda Livgood

No ARTG number

- The CRP decided to treat the complaint as withdrawn under regulation 42ZCAF(c) and referred it to the TGA because of possible food interface issues and a possible breach of section 42DL(1)(g) of the Act (the product may not be entered in the ARTG).
- The TGA website was searched (2019/03/24):
 - There were no matching results for **Ayurda Livgood**
 - There is still no ARTG entry and the product continues to be promoted as a dietary supplement.
 - Failure of the TGA to act on CRP referrals was common.

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TGA response to complaints referred from CRP*

Integrity in Healthcare Advertising

- The CRP had two reasons for forwarding complaints to the TGA:
 - Enforcement required (non-compliance with determinations);
 - Regulatory action needed (multiple similar complaints).
- Over the life of the CRP (1999 to 30 June 2018) 3185 complaints were dealt with; of these 755 were sent to the TGA.
- Of these, only 77 (10%) published outcomes could be found on the TGA website.

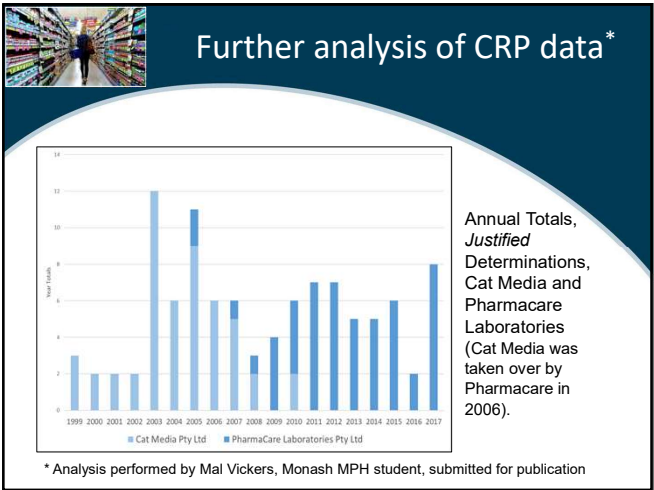
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Further analysis of CRP data*

Company	Complaints
Estee Lauder Pty Ltd	100
Nutrition Systems Pty Ltd	100
Concord International Trading Pty Ltd	100
Key-Sun Laboratories Pty Ltd	100
Metagenics Pty Ltd	100
Sigma Company Ltd	100
Sandoz Australia Pty Ltd	100
Chemist Warehouse Group	100
Brauer Natural Medicine Pty Ltd	100
Rackitt Benckiser Australia Pty Ltd	100
Bayer Australia Ltd	100
Johnson & Johnson Pacific Pty Limited	100
Procter & Gamble Australia Pty Ltd	100
Martin & Pleasance Pty Ltd	100
GlaxoSmithKline Australia Pty Ltd	100
Canus's Natural Health Pty Ltd	100
Blackmores Ltd	100
Swisse Wellness Pty Ltd	100
Pharmcare Laboratories Pty Ltd	100

Companies with more than seven accumulated justified determinations over the 18-year history of the CRP

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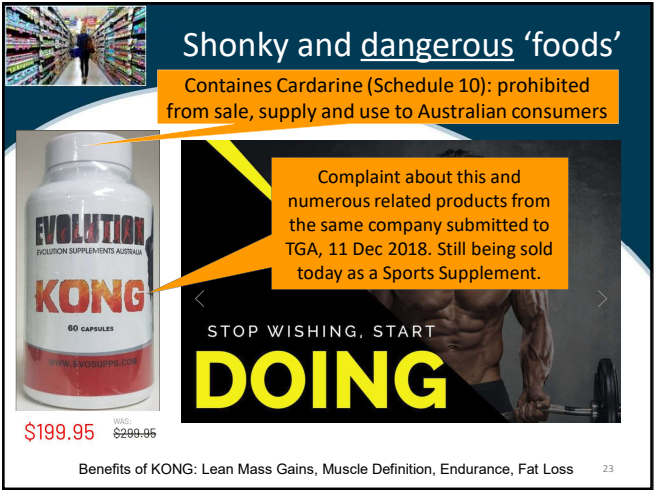
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Rules under review

- In 2018, significant changes were made to the regulatory system for advertising therapeutic goods.
- These culminated on 1 July 2018 when the CRP was abolished and the TGA took over the advertising complaint system.
- The Therapeutic Goods Advertising Code 2015 remained operational until 1 January 2019 when it was replaced by the 2018 (No 2) Code.
- Health Minister Hunt stated that the above measures, “will enable potential harms from inappropriate advertising to be comprehensively prevented.”

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Analysis of the first 6-months of the new TGA complaint system*

- At the time of analysis (17 January 2019) 628 complaint outcomes with a 2018 reference number were published on the TGA website.
- Four were judged not to be in the TGA’s jurisdiction.
- Of the remaining 624, 10 (1.6%) were judged not to breach the Code and dismissed, leaving 614.
- Of the latter, 591 (96.3%) complaints were classified as low priority and closed by sending the advertiser an educational letter. We found this rarely produced compliance.
- The remaining 23 (3.7%) complaints were classified as higher priority, all were said to be closed because compliance was achieved. In a number of cases, we disagreed.

* Analysis performed by Mal Vickers, Monash MPH student, submitted for publication

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Analysis of the first 6-months of the new TGA complaint system*

- Several complaints submitted in July 2018 have yet to have outcomes published.
- These include ongoing advertisements for FatBlaster & FatMagnet products from Pharmacare Laboratories.
- Concerns about complementary medicine weight loss products were published in 2008. Subsequently, numerous complaints about these products have been upheld by the CRP and more have been submitted to the TGA.
- Advertising compliance with these classes of products is clearly a long-standing systemic issue; it has yet to be tackled by the TGA.

* Analysis performed by Mal Vickers, Monash MPH student, submitted for publication


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Analysis of the first 6-months of the new TGA complaint system

- There are limitations of our analysis.
- Regardless, Minister Hunt’s assertion that the new complaint system , “will enable potential harms from inappropriate advertising to be comprehensively prevented” has not been realised.
- In our opinion, the TGA’s new complaint system is worse than the system it replaced. There are many issues of concern including:
 - The extremely high rate of non-compliant advertisements,
 - The risk-based triage system,
 - Lack of transparency of the new complaint system.
 - The TGA KPIs.

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Do consumers trust the TGA?

- During June and July 2018 the TGA conducted its first ever a survey of Australian adults.
- Responses were received from a random population sample (Panel) and an opt-in sample sourced through known TGA contacts, networks and consumer stakeholders.


Agreed complementary medicines are:	Panel (n=1045)	Opt-in (n=684)
Appropriately regulated	32.2%	14.5%
Trusted	37.6%	23.9%
Safe	38.5%	25.8%

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

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Conclusion



- The critique by Commissioner Haynes on regulatory failure in Australia’s financial services industry is equally applicable to the regulation of therapeutic claims for medicines and food.
- 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 and consumer detriment.

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Meanwhile:

March 20, 2019

CSIRO profiting from weight loss pill with no scientific backing

Complaint to TGA: Blackmores Ltd, ARTG: 285746, Metabolic C12, TGA Ref: AC-K1XPSTX/2019.

I allege the claims for this product breach many sections of the Therapeutic Goods Advertising Code (no 2) 2018.

For example, the 'Clinically tested' claim is invalid as it relates to a small, short-term, pilot study that investigated energy intake; not weight loss.

The claim, "Helps to assist weight loss by controlling hunger" is equally invalid as the study did not investigate weight loss.

Etc.

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So, what to do?

- Expand the Therapeutic Goods Advertising Code to a Therapeutic Claims Advertising Code?
 - Submissions by Choice, FSM, PHAA to the Senate Community Affairs Legislation Committee on the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017.
- "It is beyond the scope of the Therapeutic Goods Act, and potentially the Commonwealth's constitutional powers, for the TGA to manage complaints related to foods that make health claims".
 - Submission by Department of Health.

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So, what to do?

- Get the ACCC to act using s.18 of the Competition and Consumer Act 2010 which prohibits misleading and deceptive conduct?
- "While this is ultimately a matter for government, the ACCC is not in a position to step in where another regulator has resource constraints or makes a different assessment of priorities given our broad consumer and competition remit".
 - Submission to the TGA consultation: Options for the future regulation of 'low risk' products.

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Consumers Health Regulators Group

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1 June 2018

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Why not add FSANZ to this group and put the consistent and effective regulation of health claims on their agenda?

The members of the Group are the Australian Competition and Consumer Commission (current chair), the Australian Health Practitioner Regulation Agency (which works in partnership with 14 National Boards in the National Registration and Accreditation Scheme), the Private Health Insurance Ombudsman, the Therapeutic Goods Administration, the NSW Health Consumer Complaints Commission and the Victorian Health Complaints Commissioner. The NSW Commissioner for Fair Trading and Consumer Affairs Victoria participate in the Group as observers.

Group members exchange information, including about emerging issues of interest or concern, and to ensure responsibilities and functions of each regulator within the consumer health industry are understood and consistently applied.

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So, over to you, what to do?

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