



Food-medicine interface problems: The need for reform

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PLEASE NOTE: The TGA does not regulate:

- Health Services
- Cosmetics
- Health insurance
- Foods
- Veterinary medicine
- Chemicals

If you submit a complaint relating to a product not regulated by the TGA, we will endeavour to forward the complaint to the appropriate agency. However this may result in a delay in your complaint being considered.

For further information on what the TGA can and can't do, or if you are unsure if your product is classified as a food, cosmetic or therapeutic good, please review the links in the Important Information box.

Food-Medicine Interface Guidance Tool (FMIGT)

Manufacturers and importers of products need to know whether the products are regulated as therapeutic goods or as food because different regulatory requirements apply.

Consumers may also want to check if the products they are using are classified and regulated suitably.

Before using this tool, you are encouraged to familiarise yourself with the [basics of food and medicine and regulation](#).

Underneath each question is more information to help you make your decision. For a full explanation of each question, including real-world examples where applicable, see the [FMIGT questions - explanation and information](#).

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Food and medicine regulation

- Over recent years, health claims have been made in relation to a wider range of products, including products that have traditionally been regarded as food.
- In 2013, a FSANZ Food Standard (Standard 1.2.7) set out rules for the use of nutrition content and health claims on food labels and advertisements.
- Products that are classed as therapeutic goods (including medicines) are regulated by the TGA at a federal level while foods (including many that make health claims) are predominantly regulated by state and territory food regulatory bodies.

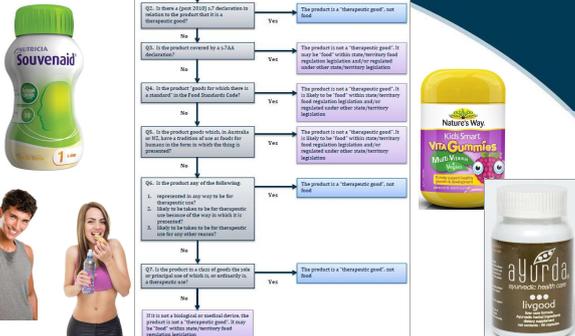
It's swallowed and makes health claims - so is it a medicine or food?

- Use the Food-Medicine Interface Guidance Tool, endorsed by the states and territories

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Food-Medicine Interface Guidance Tool (FMIGT)



Q1. Is the product for oral use for humans?

Q2. Is there a (post 2010) s.7 declaration in relation to the product that it is a therapeutic good?

Q3. Is the product covered by a s.7AA declaration?

Q4. Is the product 'goods for which there is a standard' (Food Standards Code)?

Q5. Is the product 'goods which, in Australia, are, or are intended to be, used in the same way as the food to which they relate' (Food Standards Code)?

Q6. Is the product in any way to be for therapeutic use for any other reason?

Q7. Is the product in a class of goods the sale or purchase of which is, or will likely be, regulated under other state/territory legislation?

Q8. Is there a biological or medical device, the manufacture or sale of which is, or will likely be, regulated under other state/territory legislation?

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Souvenaid - FMIGT



- Is the product for oral use for humans? (Yes)
- Is there a (post 2010) [s.7 declaration](#) in relation to the product that it is a therapeutic good? (No)
- Is the product covered by a [s.7AA declaration](#)? (No)
- Is the product 'goods for which there is a standard' in the [Food Standards Code](#) e.g.
 - 1.2.7 (Nutrition, health and related claims)?
 - 2.6.2 (Non-alcoholic beverages and brewed soft drinks)?
 - 2.6.4 (Formulated Caffeinated Beverages)?
 - 2.9.4 (Formulated supplementary sports food)?
 - 2.9.5 (Food for special medical purposes)? (Yes, claimed to be so?)

A The product is not a 'therapeutic good'. It is likely to be 'food' within state/territory food regulation legislation and/or regulated under other state/territory legislation

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Souvenaid



Souvenaid® is a Food for Special Medical Purposes for the dietary management of the early stages of Alzheimer's disease and must be used under medical supervision. Consult with your doctor, nurse or pharmacist for advice.

Channel 9 Story On Benefits Of Souvenaid

Listen to what patients and experts are saying about the benefits of Souvenaid.

[Watch Video](#)

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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

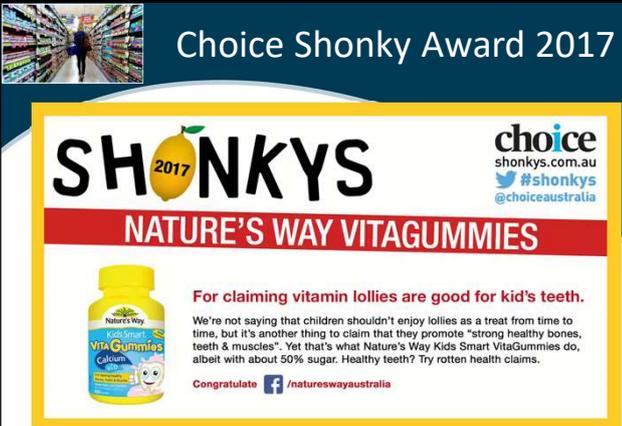


Standard 2.94 sports food

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Choice Shonky Award 2017



SHONKYS 2017
NATURE'S WAY VITAGUMMIES

choice
shonkys.com.au
#shonkys @choiceaustralia

For claiming vitamin lollies are good for kid's teeth.

We're not saying that children shouldn't enjoy lollies as a treat from time to time, but it's another thing to claim that they promote "strong healthy bones, teeth & muscles". Yet that's what Nature's Way Kids Smart VitaGummies do, albeit with about 50% sugar. Healthy teeth? Try rotten health claims.

Congratulate /natureswayaustralia

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

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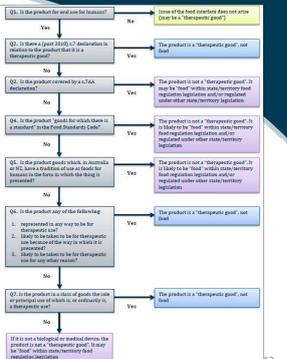
Kids gummies: food or medicine?



No ARTG ID



ARTG ID: 280983



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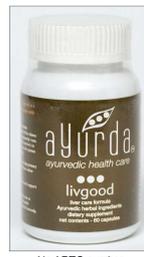
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Problems with kids sugar coated gummies

- 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



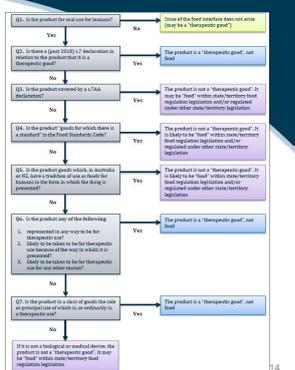
A natural formulation that helps the liver expel the build up of toxins from the liver which accumulate from a diet that includes fried & highly processed foods.

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

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

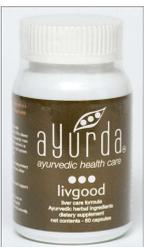
are used in Ayurveda to protect the liver from the impact of overindulgence.

Quantity - 60 capsules
 Price: \$36.00 inc GST



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Complaint sent to CRP, 20 Nov 2017



- 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



- 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*

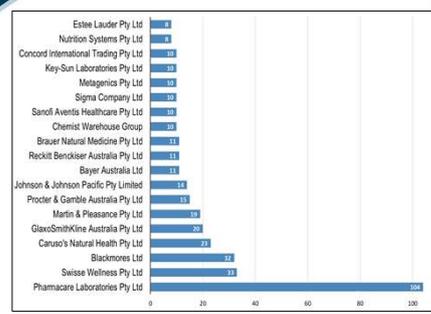



- The CRP had two reasons for forwarding complaints to the TGA:
 - Enforcement required (non-compliance with determinations);
 - Regulatory action needed (multiple similar complaints).
- Over the life of the CRP (1999 to 30 June 2018) 3185 complaints were dealt with; of these 755 were sent to the TGA.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

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

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Further analysis of CRP data*

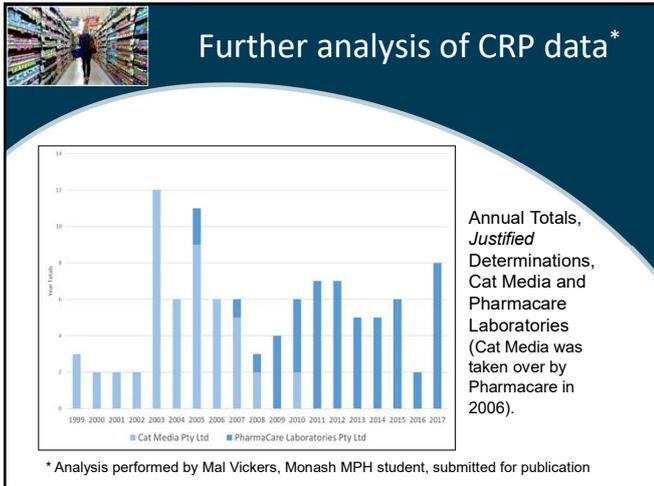


Company	Number of Complaints
Estee Lauder Pty Ltd	1
Nutrition Systems Pty Ltd	1
Concord International Trading Pty Ltd	1
Key-Sun Laboratories Pty Ltd	1
Metagenics Pty Ltd	1
Sigma Company Ltd	1
Sandoz Aventis Healthcare Pty Ltd	1
Chemist Warehouse Group	1
Brauer Natural Medicine Pty Ltd	1
Reckitt Benckiser Australia Pty Ltd	1
Bayer Australia Ltd	1
Johnson & Johnson Pacific Pty Limited	1
Procter & Gamble Australia Pty Ltd	1
Martin & Pleasance Pty Ltd	1
GlaxoSmithKline Australia Pty Ltd	1
Casus's Natural Health Pty Ltd	1
Blackmores Ltd	1
Swisse Wellness Pty Ltd	1
Pharmcare Laboratories Pty Ltd	1

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

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

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What does Pharmicare Laboratories produce?

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From shonky complementary medicines to shonky foods

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Shonky and dangerous 'foods'

TUESDAY 17 APRIL 2018 10:36AM

By James Purtil

SARMs: The massive black market in illegal bodybuilding 'research chemicals'

First it was prohormones, then it was peptides - now a new black market sports supplement hyped as the "holy grail" has taken the Australian market by storm.

Complaint to CRP, 29 March 2018, referred to TGA, 5 April 2018 (2018/03/015) AusLabs SAMS, STACKS, PCT & SUPPORT, PEPTIDES. No outcome to-date; products still being sold today.

<https://www.abc.net.au/triplej/programs/hack/massive-blackmarket-in-sarms-research-chemicals/9666006>

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Shonky and dangerous 'foods'

Contains Cardarine (Schedule 10): prohibited from sale, supply and use to Australian consumers

Complaint about this and numerous related products from the same company submitted to TGA, 11 Dec 2018. Still being sold today as a Sports Supplement.

STOP WISHING, START DOING

Benefits of KONG: Lean Mass Gains, Muscle Definition, Endurance, Fat Loss

\$199.95 (was \$299.95)

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TGA regulation

<http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be>

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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 26

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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 27

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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> 29

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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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