Food-medicine interface problems: Dr Ken Harvey's presentation to the FSANZ Consumer and Public Health Dialogue, 27 March 2019 and discussion points.

Summary

The regulation of health claims for foods and medicines is inconsistent; complaint systems are problematic, no effective penalties are applied for documented breaches of the law, and shonky (and dangerous products) are proliferating. The consequence is consumer detriment. There needs to be one ethical Code governing the advertising of health claims for food, medicines and medical devices and one timely, effective and accountable complaint system, with penalties that deter the profit that currently accrues from breaking the law.

The first example illustrated was Souvenaid, a product self-declared by Nutricia as a food for special medicinal purposes for the treatment of mild Alzheimer's disease. FSANZ Standard 2.9.5 (food for special medical purpose) means a food formulated for individuals who have special medically determined nutrient requirements, whose dietary management cannot be completely achieved without the use of the food and is used under medical supervision.

I am unaware that patients with mild Alzheimer's disease have special medically determined nutrient requirements. Their dietary requirements can be adequately managed by a Mediterranean diet. In addition, the product is being sold over the Internet without medical supervision.

Furthermore, if this product had been classified as a medicine, the claims made would have breached many sections of the Therapeutic Goods Advertising Code 2015. However, as this product was determined to be a food, the Code did not apply. Sponsors of food are held to a lower ethical standard than the sponsors of medicines; a concern expressed by both consumer organisations and Complementary Medicines Australia.

It was suggested that Standard 2.6.2 (which includes sports drinks) and Standard 2.9.4 (sports food) primarily benefits companies marketing them; not most consumers.

Problems were also noted with sugar coated "Vita gummies" (pastilles) targeting children. 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. These products are unhealthy, poorly regulated and exploitative.

The TGA has failed to adequately deal with complaints about numerous products purporting to control weight, such as Fat Blaster, Fat Magnet and Reducta from Pharmacare Laboratories; Ayurvedic (traditional) medicines that claim to protect the liver from overindulgence and numerous "sports supplements" purporting to benefit muscle definition, endurance and fat loss. The latter products have been found to contain Schedule 4 (prescription only) or Schedule 10 (banned) ingredients. They remain on the market.

It was noted that complaints about food claims were handled by State & Territory Food Authorities some of whom delegate this responsibility to local Councils. The handling and recording of these complaints were inconsistent as food safety issues usually received a higher priority. Also, there is no central collation of data about these complaints or their outcomes.

A recent research paper showed that allowing industry to self-substantiate general level food-health claims resulted in many that could not be validated by independent investigation.

I suggested that the ACCC should invite FSANZ to join the Consumers Health Regulators Group and the topic of consistent and effective regulation of health claims should be a high priority agenda item for this group.

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Dr Harvey's presentation[1] made the following points:

1. Allowing industry (Nutricia) to self-declare Souvenaid a food for special medicinal purposes for the treatment of mild Alzheimer's disease (under Standard 2.9.5) appeared to be a breach of the Standard.

   Standard 2.9.5 (Food for special medical purpose) means a food specially formulated for the dietary management of individuals who have special medically determined nutrient requirements and whose dietary management cannot be completely achieved without the use of the food and is intended to be used under medical supervision.

   I do not believe it has been shown that patients with mild Alzheimer's disease have special medically determined nutrient requirements. Their dietary requirements can be adequately managed by a Mediterranean diet. In addition, the product is being sold over the Internet without 'medical' supervision.

   A complaint forwarded to the NSW Food Authority did not address whether Souvanaid fulfilled the requirements of a 'food for special medical purpose'. In response to concern about consumers ability to purchase this product over the Internet, the reply noted that 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.

2. The complaint noted that claims made for Souvenaid would breach many sections of the Therapeutic Goods Advertising Code 2015 if this product was a medicine. However, as the NSW Food Authority declared Souvenaid to be a food, they also determined it was not subject to the requirements of the Code or the associated Guidelines.

3. As I have publicly commented before, this case raises important issues about the inconsistency of regulations for medicine and food. If there is no ethical Code for claims about food, sponsors of food are held to a lower ethical standard than the sponsors of medicines; a concern expressed by consumer organisations and Complementary Medicines Australia. This may also account for the increasing number of products making health claims purporting to be dietary supplements (foods).

4. Standard 2.9.5 also appeared to have contradictory clauses.

   2.9.5-4: A claim in relation to a food for special medical purposes must not (a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition.

   2.9.5-10: (c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated.

5. It was noted that Standard 2.6.2 (which includes sports drinks) and Standard 2.9.4 (sports food) were controversial if this product was a medicine.

   Submissions to proposal 1030 pointed out that only endurance athletes benefit from these products. Regardless, they are promoted to those who mainly don't need them.

   Australian Dietary Guidelines note that consumption of sports drinks should be limited as excessive caloric intake can increase the risk of overweigh and obesity. These products also have adverse effects on dental health due to their acidic and sugary nature.

   It was concluded that these standards benefit companies marketing them; not consumers.

6. Problems were noted with sugar coated gummies (pastilles) targeting children. These products can contain vitamins, minerals, fish oil and vegetable extracts. Some are regulated as foods, others as medicines.

[1] Available at: https://medreach.com.au/wp-content/uploads/2019/03/FSANZ_Harvey_Canberra.pdf

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.

My colleagues and I have described these products as, "unhealthy, poorly regulated and exploitative". Who is responsible: FSANZ or the TGA?

7. Numerous products self-declared to be "dietary or sports supplements" have had complaints submitted to the old Complaint Resolution Panel (CRP) alleging they breached the Therapeutic Goods Act &/or the Therapeutic Goods Advertising Code. Many were referred from the CRP to the TGA for regulatory action; few have received a published outcome.

   Referrals included numerous products purporting to control weight, such as Fat Blaster, Fat Magnet and Reducta from Pharmacare Laboratories; products that claim to protect the liver from the impact of overindulgence containing herbs used in Ayurvedic (traditional) medicine and numerous "sports supplements" purporting to benefit muscle definition, endurance and fat loss. The latter products have been found to contain Schedule 4 (prescription only) or Schedule 10 (banned) ingredients. They remain on the market.

8. The CRP was abolished and the TGA took over the therapeutic good complaint system on 1 July 2018. Over the life of the CRP (1999 to 30 June 2018) 3185 complaints were dealt with. Companies with more than seven accumulated justified determinations were tabulated by Monash MPH student, Mal Vickers (submitted for publication).

   One company stood out in this analysis - Pharmacare Laboratories. Over the life of the CRP, Pharmacare had 104 complaints upheld by the CRP, around three times more than Swisse Wellness and Blackmores, which respectively had the second and third highest number of justified complaints. Over the 18-year life of the CRP Pharmacare breached the Code every year; exemplifying the failure of the complaint system to impact on unlawful behaviour.

   The CRP had no power to enforce their determinations. They sent 755 upheld determinations to the TGA, either because of non-compliance with determinations (enforcement required), or because they had received multiple similar complaints (regulatory action needed).

   Of complaints referred to the TGA, only 77 (10%) published outcomes could be found on the TGA website.

9. During 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."

   An analysis of the first 6-months of the new TGA complaint system was conducted by Monash MPH student, Mal Vickers (submitted for publication). 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 low priority accorded some complaints was also hard to understand. For example, one complaint noted 33 previous complaints upheld by the CRP and 22 additional complaints sent to the TGA because regulatory action was required. The TGA appeared to have taken no action about these referrals and yet another complaint about the same matter was merely classified as low priority.

The remaining 23 (3.7%) complaints were classified as higher priority, all were said to be closed because compliance was achieved. In many cases, we disagreed that compliance had been achieved.

While there are limitations of this analysis, Minister Hunt's assertion that the new complaint system, "will enable potential harms from inappropriate advertising to be comprehensively prevented" has clearly 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 triage system that results in most complaints being accorded a low priority; the lack of transparency (no details about low priority complaints are published) and the KPIs which appear to prioritise complaint closure rather than compliance being achieved.

10. 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. Overall, the responses showed considerable concerns held by survey participants relating to statements about complementary medicines.

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%

11. I suggested that the critique by Commissioner Haynes on regulatory failure in Australia's financial services industry was 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.

12. So, what to do?

    Choice, Friends of Science in Medicine and the Public Health Association of Australia have suggested expanding the Therapeutic Goods Advertising Code to a Therapeutic or Health Claims Advertising Code.

    To which the Department of Health responded, "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".

    Another suggestion was for the ACCC to act using s.18 of the Competition and Consumer Act 2010 which prohibits misleading and deceptive conduct.

    The ACCC responded, "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".

I suggested that FSANZ should be added to the ACCC's Consumers Health Regulators Group and the topic of consistent and effective regulation of health claims should be put as a high priority item on their agenda.

There needs to be one ethical Code governing the advertising of health claims for food, medicines and medical devices and one timely, effective and accountable complaint system, with penalties that deter the profit that currently accrues from breaking the law.

During discussion:

13. [redacted] noted that complaints about food claims were handled by State & Territory Food Authorities, some of whom delegate this responsibility to local Councils.

    She agreed that the handling, outcomes and recording of these complaints was inconsistent as food safety issues usually received a higher priority. Also, there was no central collation of data about these complaints or their outcomes.

14. [redacted] mentioned a recently published paper of which she was a co-author (attached).[2]

    This study assessed the rigour of self-substantiation by industry of general level food-health claims as allowed by FSANZ. During the study period, there were 67 food–health relationships notified by 38 different food companies. Four relationships were excluded as they were notified by New Zealand-based companies. Of the 63 Australian-notified food–health relationships, 33 relationships (52%) from 20 companies were deemed to have enough published evidence to substantiate the relationship and were not investigated further.

    Of the remaining 30 relationships, 3 were removed from the FSANZ website before being assessed by the project team. At the time of publication, one relationship was still being assessed by the project team.

    The 27 different food–health relationships that were referred to the state government agencies for assessment came from nine different companies; these were investigated by four different state government agencies.

    Of the 27 claims investigated; 8 (30%) were judged to be substantiated by an independent assessment of the evidence available; 12 (44%) could not be substantiated, while the investigation of 7 (26%) continued. The paper noted the health relationship on influenza of Elderberry Fruit Extract (Sambucus nigra) was one found to have insufficient evidence to justify a high-level food-health claim.

    This Pharmacare Laboratories complementary medicine product also had several complaints upheld by the old Complaint Resolution Panel: http://www.tgacrp.com.au/complaint-register/?_search=Sambucol

    This shows that a common food-medicine health claims complaint system would avoid this duplication of effort.

Dr Ken Harvey
Associate Professor
Public Health and Preventive Medicine
Monash University
E: kenneth.harvey@monash.edu

[2] https://www.researchgate.net/publication/331500165_How_effective_is_food_industry_self-substantiation_of_food-health_relationships_underpinning_health_claims_on_food_labels_in_Australia