

# The Australian obesity epidemic and the regulation of complementary medicine weight loss products

Ken Harvey<sup>1</sup>

Of 23 OECD countries, Australia has the fifth-highest rate of obesity and overweight. Obesity is second only to smoking as a risk factor for disease.<sup>1</sup> Reducing the increasing number of overweight and obese people requires integrated policy initiatives that address an obesogenic environment, including sedentary behaviour, unhealthy eating habits and misleading advertising.<sup>2</sup> The Therapeutic Goods Administration (TGA) is responsible for advertisements for medicines. This paper focuses on the role of the TGA.

Choice and other advocacy groups raised concerns about the regulation of complementary medicine weight loss products in 2008.<sup>3</sup> At that time, the number of listed weight-loss products, and complaints about their advertising, was increasing. The increase appeared to be the perverse outcome of regulatory policy that did not evaluate these products for efficacy and charged less for listing a product than more rigorous registration. The complaint system was overloaded, under-resourced and had no power to enforce determinations. The system required regulatory reform.

In 2015, the *Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods* report recommended significant changes.<sup>4</sup> In response, the government introduced a new legally enforceable Therapeutic Goods Advertising Code, the TGA acquired enhanced compliance and enforcement powers and industry educational resources were augmented. Compliance powers now included regulatory obligation (warning letters, infringement notices (fines),

## Abstract

**Objective:** Investigate the response of the Therapeutic Goods Administration's (TGA) new advertising complaint system to resubmitted complaints about complementary medicine weight loss products previously upheld by the Complaint Resolution Panel.

**Methods:** Between July 2018 and July 2019, complaints about a convenience sample of 22 complementary medicines by eight sponsors, advertised on 140 different internet sites (cases), were resubmitted to the TGA. FatBlaster products featured. Follow-up occurred in February 2021.

**Results:** A search of the TGA advertising complaints database found 'no result' for 84% of the 140 cases submitted. Despite the TGA delisting three products and sponsors delisting ten others, all products complained about were still being advertised. Some products had minor changes in imagery but not claims. The sponsor (Cat Media, Naturopathica) had listed three new FatBlaster weight loss products.

**Conclusions:** The TGA failed to protect consumers from ineffective weight loss medicines.

**Implications for public health:** Weight loss medicines with misleading and deceptive claims are likely to divert users from evidence-based weight loss activities. The TGA should ask for the evidence supporting promotional claims for these products and, if this is lacking, delist the entire class of products. For recalcitrant sponsors who repeatedly make egregious claims, civil and criminal penalties should be applied.

**Key words:** complementary medicines, regulation, promotion, obesity epidemic

enforceable undertakings, injunctions, and civil and criminal penalties.<sup>5</sup> On 1 July 2018, the TGA took over the advertising complaint system. In 2020, detailed reviews of Australian complementary medicines advertising policy before and after July 2018 were published.<sup>6,7</sup>

Before July 2018, the Therapeutic Goods Advertising Complaint Resolution Panel (CRP) upheld more than 30 complaints about weight loss products, including FatBlaster.<sup>8</sup> The CRP had repeatedly judged these claims misleading and deceptive, but the advertisements continued. This paper documents the TGA's new advertising complaint system response to the resubmission of these complaints.

## Methods

Between July 2018 and July 2019, complaints about a convenience sample (selected by the author) of 22 complementary medicine weight loss products, by eight sponsors, advertised on 140 different Internet sites (cases), were submitted to the TGA (Table 1). FatBlaster products (Cat Media, Naturopathica) featured. Follow-up occurred in February 2021.<sup>9</sup> The TGA advertising complaint database was searched for outcomes using the case numbers allocated. If nothing was found, a broader search of the TGA site was conducted. A new internet search was conducted on products

1. Faculty of Health Sciences and Medicine, Bond University, Queensland

**Correspondence to:** Dr Ken Harvey, Faculty of Health Sciences and Medicine, Bond University, 14 University Drive, Robina QLD 4226; e-mail: kharvey@bond.edu.au

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complained about to see if the advertising had changed.

### Results

The TGA advertising complaints database search found 'no result' for 84% of the 140 cases submitted (Table 2). Eleven per cent were said to be resolved by the TGA contacting the advertiser (all for Blooms Melt or Blooms Svelte). Five per cent were closed by sending the advertiser a regulatory obligation letter (all for Impromy Metabolic C12).<sup>8</sup> Regardless, at the time of writing, all 22 products continued to be advertised.

A broader search of the TGA website found that Healthy Care Forskolin had been cancelled by the TGA in 2016. An advertising direction notice dated 20 November 2019 was found for FatBlaster Clinical. This required the sponsor to cease making claims that the product could assist with weight loss; it also banned the image of a slim female torso that appeared on the label. One month later, this product was cancelled from the Australian Register of Therapeutic Goods (ARTG) by the TGA.<sup>10</sup>

On 19 November 2020, the TGA issued an infringement notice for \$13,320 to the sponsor (Cat Media, Naturopathica) for the alleged unlawful advertising of FatBlaster Apple Cider Vinegar and Garcinia Max, which lacked a current ARTG listing. On 23 December 2020, the TGA also cancelled the ARTG listing of FatBlaster FatMagnet.<sup>10</sup> There is no mention of these actions in the TGA advertising complaint database.

Ten other products advertised were also no longer listed on the ARTG, including FatBlaster Apple Cider Vinegar and Garcinia Max (presumably cancelled by the sponsor). Eleven products had had some changes made to their imagery but not their claims. Meanwhile, Cat Media, Naturopathica had listed new FatBlaster weight loss products

on the ARTG. These included FatBlaster Platinum Metabolism, containing the same SLENDACOR™ ingredients of the cancelled FatBlaster Clinical, and FatBlaster FatMagnet Max with a new ingredient.<sup>9</sup>

### Discussion

Obesity is an increasing public health problem. Overweight and obese people are inevitably attracted to a pill promising a 'quick fix'. Complementary medicine sponsors cater to this vulnerability by marketing a succession of products that imply they reduce weight by their names, claims and product imagery. These misleading and deceptive claims are likely to divert users from evidence-based weight loss activities. They are also a clear breach of section 9(b) of the Therapeutic Goods Advertising Code which states, "Advertising for therapeutic goods must be ... truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons...".<sup>11</sup>

The TGA's new complaint system lacks transparency. No result was found for more than 80% of complaint cases submitted. The remaining cases were said to be closed either by the TGA directly contacting the advertiser or sending a regulatory obligations letter. This letter informs the advertisers of alleged non-compliance in a complaint, provides them with educational material, and states the TGA will take no further action.<sup>12</sup> While these letters might produce compliance, no details of the product, sponsor or alleged breaches are present in the complaint database, unlike previous CRP determinations. Consumers, industry, and other advertisers are unaware of the problems raised.

The TGA has explained their failure to deal with many complaints as a result of the unprecedented number of complaints received in the first two years of operation of

the new system.<sup>12</sup> The lack of transparency for complaints that have been dealt with is due to the TGA's 'risk-based' approach of classifying most complaints as 'low priority' and not formally determining if a regulatory breach has occurred. Because no determination has been made, no details of the complaint are published.<sup>13</sup>

A few cases elicited more definitive action, such as advertising direction notices and product cancellations. However, it is not easy to find these outcomes on the TGA website; it would be better if they were also added to the complaint database.

One response of sponsors to TGA product cancellation is to relist comparable products. FatBlaster Clinical was replaced by FatBlaster Platinum + Thermoburn and FatBlaster Platinum Metabolism. The cancelled FatBlaster FatMagnet also has a new listing: FatBlaster FatMagnet Max with a new but equally ineffective ingredient (*Opuntia ficus-indica*). Another response is to reformulate cancelled products as food 'shakes'.<sup>9</sup>

Other products had their listings cancelled by the sponsor, but promotion continued. A sponsor may cancel a listing to abort TGA post-market compliance reviews. The TGA assesses around 160 listed products a year (out of more than 10,000). The results can be found (with difficulty) in TGA annual performance statistics reports.<sup>14</sup> Over the past five years, on average, around 75% of products assessed were found non-compliant, mainly because companies could not produce evidence to substantiate claims for efficacy. In 2018–20, 15% of 376 post-marketing reviews were aborted by sponsors delisting their products following a request for information by the TGA.

Once cancelled, a therapeutic good cannot be imported, manufactured or exported from Australia. However, it can be sold by retail outlets until the stocks run out.<sup>15</sup> No warning is provided to consumers that they may be purchasing a product that has been cancelled because, for example, the TGA found, "insufficient evidence to support the indications for the product" for FatBlaster FatMagnet.<sup>10</sup> Advertising a product cancelled from (or not on) the ARTG is a breach of the Therapeutic Goods Act, but it appears that the TGA does not follow-up cancellations to see if advertising is still occurring. Consumers would be assisted if this was done.

The *Therapeutic Goods Amendment Bill (No. 4) 2000*, allowed 'low-risk' complementary medicines (AUST L) to be listed automatically

**Table 1: Complaints# submitted to TGA.**

Weight loss products involved	Product sponsors	Advertisements (cases <sup>a</sup> ) documented (advertised by different Internet pharmacies, product sponsors, etc.)
22	8	140

Note:

a: On receipt of a complaint involving multiple advertisers the TGA allocates a reference number for the complaint and case numbers for the individual advertisers involved.

**Table 2: Complaint outcome (from searching the TGA complaint database for the allocated case number).**

No result found	Resolved by contacting advertiser	Closed by sending a regulatory obligations letter
118 (84%)	15 (11%)	7 (5%)

in the Australian Register of Therapeutic Goods (ARTG) following the self-assessment by sponsors of regulatory compliance.<sup>16</sup> This means that the TGA cannot prevent questionable products being listed or marketed; it can only raise issues afterwards. Regardless, because sponsors often relist cancelled products under new names, the TGA could proactively scan new ARTG listings for sponsors of products that have been recently cancelled. It could also scan the ARTG for keywords that might indicate problematic advertisements, such as 'fat', 'weight' and 'craving', and review products as required.

In 2019, the TGA introduced the *Therapeutic Goods (Permissible Indications) Determination (no. 1) 2019* as part of the advertising reforms.<sup>17</sup> The aim was to limit 'advertising creativity'. However, the industry was allowed to create the list of permitted indications. As a result, 86% of 1,021 indications can now be justified by 'traditional use' rather than scientific evidence. This has essentially removed the need for 'complementary medicines' to have a scientific base. Not surprisingly, this review of weight loss advertisements found increasing use of 'traditional use' justifications.

At least 31 permissible indications relevant to weight loss products lack supporting evidence. They include, 'Aids/assists abdominal fat loss', 'Promote/enhance feeling of satiety' and 'Enhance/promote/increase temporary [3-month] weight loss'. The latter is irreconcilable with the TGA *Evidence Guidelines* which state a weight loss study duration should be 6 months.<sup>18</sup> These indications require a label stating, "When used in conjunction with a program of reduced intake of dietary calories and increased physical activity". Despite that caveat, these indications lack evidence and facilitate the proliferation and promotion of ineffective, costly weight loss products.

In August 2020, an independent review of the first two years of the TGA's compliant system was published.<sup>19</sup> The study noted an unexpectedly high volume of complaints since the TGA took over the advertising complaints system, producing a large and growing backlog. ThinkPlace Pty Ltd (review consultants) stated that providing more resources would not be in the public interest. Instead, it recommended a more cost-effective and efficient approach: amalgamating all complaints into an information database from which the TGA could consider compliance priorities.

As a result, complaints are now closed by sending complainants a letter stating that their complaint will be used for 'intelligence' to set priorities. The TGA says that risk assessment informs whether a complaint is converted into a case for investigation or stored in their information database to determine future compliance priorities. Therapeutic goods associated with COVID-19 were declared 'priority 1', while weight loss, hangover and four other products groups were said to be 'priority 2'.<sup>20</sup> A focus on COVID-19 has stimulated the TGA to deal with some of these complaints more effectively.<sup>21</sup> However, apart from token action on a few individual products, no systemic action has been taken on weight loss products.

In conclusion, the TGA states that choosing therapeutic goods wisely depends on accurate, balanced advertising that does not mislead or take advantage of the vulnerability of consumers in the health product market.<sup>12</sup> I agree. The TGA would be more effective if it dealt with misleading weight loss (and hangover) products that undermine public health as a group, not as isolated individual complaints. Why not ask industry to provide evidence supporting their complementary medicine weight loss claims? Also, can industry justify the permitted indications they put up for weight loss? If evidence is lacking, why not delist the entire class of products? Finally, for recalcitrant sponsors who repeatedly make egregious claims, civil and criminal penalties are required.

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