



Session W15: Sydney ARCS Scientific Congress, 5-6 June 2013

Listed Complementary Medicines: A Consumer perspective

Dr Ken Harvey MB BS, FRCPA
<http://www.medreach.com.au>




Talk outline




A Big Mac and fries needs 5 Undoit® pills.




- Disclosure of interests
- Media perceptions
- Four illustrative complaints:
 - SensaSlim®
 - Undoit®
 - SENSA®
 - Berocca®
- Problem summary
- TGA reform?

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Disclosure of interests





- Member:
 - Expert group that wrote the WHO Ethical Criteria for medicinal drug promotion.
 - Therapeutic Guidelines Limited.
 - PHARM Committee that devised the Quality Use of Medicines plank of Australian Medicines Policy.
- Consumer representative (Choice):
 - Government Working Group on Promotion of Therapeutic Products.
 - TGA Transparency Review Panel.
 - TGA Working Group on Regulatory Framework for Complementary Medicines.
 - Government Natural Therapy Review Advisory Committee.

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Media perceptions



29 November 2011, 2:54pm AEST



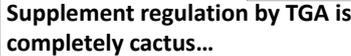
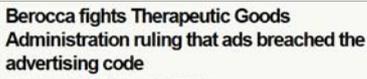
19 April 2012, 9:57am AEST



22 October 2012, 11:05am AEST



The Sydney Morning Herald

LUCKE VAN DER BERG • HERALD SUN • MAY 27, 2013 7:03PM

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Experience with complaints



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SensaSlim: the promotion

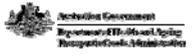


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The complaint March 18, 2011

- I submit that the claims made for this product breach
- Therapeutic Goods Advertising Code 2007,
 - Section 4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(h), 4(2)(i), 4(4), 4(5), 4(6)(b)(i) 4(6)(b)(iv), 4(7), 7(3);
- Therapeutic Goods Act 1989,
 - Section: 22(5);
- Competition and Consumer Act 2010
 - Section 18, 29(1)(a), 29(1)(f)(i), 29(1)(g), 29(1)(h);






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SensaSlim threats: March 31, 2011

LEGAL AFFAIRS

31 March 2011

Attention: Dr. Ken Harvey
Medreach Pty. Ltd
35a Mary St.
Hawthorn Vic 3122
AUSTRALIA

We are the manufacturers and marketers of the product SensaSlim Solution in Australia.

We are aware of your comments published at www.auspharmacist.net.au

We advise that we believe we have a cause of action for commercial disparagement against you personally. We also believe that Dr Matthew Capehorn, internationally respected obesity expert, has grounds for an action against you for defamation.

There is no doubt that the quotes attributed to you are false, the conclusions reached unjustified and unjustifiable, and an incorrect statement of opinion.

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SensaSlim threats: April 4, 2011

-----Original Message-----
From: Legal SensaSlim [mailto:legal@sensaslim.com.au]
Sent: Monday, 4 April 2011 3:38 PM
To: Sandra Leggat (Head, School of Public Health, La Trobe University)
Subject: Re: Complaint against Dr Ken Harvey

Dear Professor Leggat,

Can you please confirm that you have formally instructed Dr Harvey to withdraw his complaint penned under the name of La Trobe University.

If this is not the case, we will be forced to join the School of Public Health, La Trobe University in our Court action.

Your earliest reply would be appreciated.

Terry Harrison
Legal Advisor
SensaSlim Australia Pty. Ltd.

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SensaSlim action: April 19, 2011

STATEMENT OF CLAIM

COURT DETAILS	Supreme Court of New South Wales	RELIEF CLAIMED	
Court -	Supreme Court of New South Wales		
#Division	Defamation List		
#List -	Sydney		
Registry -	2011/130614	1 Payment of \$800,000.00 for damages	
Case number		2 Costs	
TITLE OF PROCEEDINGS	Sensaslim Australia Pty Ltd (ACN: 14	(If you are making a liquidated claim (ie claiming a specific amount of money),	
plaintiff	Dr. Ken Harvey (ACN: 006 919 871)	Amount of claim	\$800,000.00
First defendant	Medreach Pty Ltd (ACN: 006 919 871)	Interest	\$
Second defendant		Filing fees	\$2,142.00
		Service fees	\$
		Solicitors fees	\$
		TOTAL	\$802,142.00
FILING DETAILS	Sensaslim Australia Pty Ltd		
Filed for	Peter O'Brien 02 9376 2155		
Contact name and telephone			
TYPE OF CLAIM			
Torts - Other - Defamation			

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CRP response: April 21, 2011

Therapeutic Products Advertising Complaints COMPLAINTS RESOLUTION PANEL

Dear Dr Harvey,

Complaint 2011/03/021 SensaSlim Solution

On Wednesday 19 April 2011, the respondent for the above complaint, SensaSlim Australia Pty Ltd, provided the Complaints Resolution Panel with a copy of a signed and sealed Statement of Claim that had been presented to the Supreme Court of New South Wales on that day, which specifically relates to the matters raised in the complaint.

At the meeting of the Complaints Resolution Panel held on Thursday 21 April 2011, the Panel decided to defer consideration of the above complaint, per Regulation 42CAU(2), which states:

If, after a complaint has been made to the Panel, a proceeding begins in a court about the subject matter of the complaint, the Panel cannot deal with the complaint until the proceeding is finally disposed of.

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Newsletter 43: April 29, 2011



“This defamation action, which could be in the courts for a year or two or even longer, basically gives an iron clad protection that nobody can raise a complaint against SensaSlim to the CRP and hurt us”.

Adam T Adams

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SensaSlim: goes SLAPP

- Strategic litigation against public participation (SLAPP) is commonly brought by corporations with an intention of intimidating and silencing outspoken individuals who voice issues of public interest or concern.
- Recipients of SLAPP writs are often unable to afford the expensive and lengthy legal representation needed to defend the charges against them.



Photo by Malcolm Vickers
Victorian Skeptics

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My lawyer's response



Our Ref: CMS: 110531
6 May 2011
The Proper Officer
Sensaslim Australia Pty Limited
Level 29, Chifley Tower

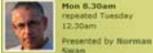
A notice of motion was filed in the NSW Supreme Court seeking orders to have the SensaSlim claim struck out and the proceedings dismissed because they disclosed no reasonable cause for the action. In addition, an order was sought that the plaintiff should pay the defendants' costs.

We refer to the statement of claim. It appears that the statement of claim is seriously defective. We raise the following matters with you:

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ABC Radio: May 16, 2011

11:30am repeated Tuesday 12:30pm
Presented by Norman Swan

Regulation of Complementary Medicines

- "There is a clinically trialled weight loss spray you have not encountered. An oral TGA approved liquid spray which claims to be the most effective slimming solution available anywhere in the world".
- These claims formed the basis of a complaint lodged with the Therapeutic Goods Administration.
- Since making the complaint Dr Harvey has been sued by the manufacturer of the product, SensaSlim Australia Proprietary Limited.

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Dr Capehorn: May 21, 2011



- "Despite requests, I've never seen evidence of the original clinical trial, and it has never been published in a peer reviewed medical journal".
- "Therefore, the White Paper holds no scientific relevance, until that original trial is published".
- "It has not been published at the European Congress of Obesity in Istanbul as suggested recently".

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ACCC v SensaSlim July 21, 2011



21st July 2011

ACCC takes court action against Sensaslim for alleged misleading claims

The Australian Competition and Consumer Commission has instituted proceedings against Sensaslim Australia Pty Ltd (Administrator Appointed) (Sensaslim), Mr Peter Clarence Foster, Mr Peter Leslie O'Brien, Mr Adam Troy Adams and Mr Michael Anthony Boyle.



- The Federal Court ordered SensaSlim to publish a notice on their web site including a statement that they had,
 - "falsely representing that the SensaSlim Solution was the subject of a large worldwide clinical trial when in fact no such trial was conducted, etc."

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In court: August 15, 2011



JUDGMENT ORDER

COURT DETAILS
Court: Supreme Court of NSW
Division: Common Law
List: Common Law General
Registry: Supreme Court Sydney
Case Number: 201100130614

TITLE OF PROCEEDINGS
First Applicant: Dr Ken Harvey
Second Applicant: Meditech Pty Ltd
First Respondent: Sensaslim Australia Pty Ltd
ACN: 16020133

DATE OF JUDGMENT ORDER
Date made or given: 15 August 2011
Date entered: 16 August 2011

TERMS OF JUDGMENT ORDER
The Court Orders that:
1. The Statement of Claim filed on 20/4/11 be dismissed.
2. The Plaintiff pay the Defendant's costs of these proceedings.

SEAL AND SIGNATURE
Signature: M. Ho
Capacity: Chief Clerk
Date: 24 August 2011

- Nicholas J. struck out the case and awarded costs.
- However, this was a pyrrhic victory as the company administrator / liquidator said there was no money left to award costs (and there are also many other claimants)!

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In court: August 15, 2011

- In addition, a new defamation claim, similar to the first, was filed in the Queensland Supreme Court by Peter O'Brien (previous Director of SensaSlim (Australia) Pty Ltd), this time for \$1,075,000.00.
- For this second case, Maurice Blackburn Lawyers offered their services pro bono.
- The 2nd case was struck out on May 28, 2012.
- The ACCC case continues.

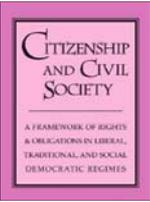
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Lessons

- I could not have defended these actions without the outstanding moral and financial support of numerous people: fellow health professionals, friends from the consumer movement, Australian Skeptics and many ordinary people.
- Thanks to their generosity (including Maurice Blackburn lawyers who acted pro bono for the second case) I did not end up out of pocket.
- The media also played a crucial role by providing extensive publicity of this ongoing saga.

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Lessons




- This response by civil society sends a strong message to those companies contemplating similar tactics against complainants.
- The publicity will be counter-productive and these cases will be fought to a successful conclusion.

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TGA v SensaSlim: 24th Nov, 2011

Home > News room > News & public notices >>

Cancellation of Sensaslim Solution from the ARTG

24 November 2011

The TGA has cancelled the listing of Sensaslim Solution (AUST L 176003) from the Australian Register of Therapeutic Goods (ARTG). The cancellation is because of a failure to comply with requirements of the Therapeutic Goods Act 1989 relating to the advertising of the product.

The cancellation is effective from 1 December 2011. From 1 December 2011, the following activities may constitute an offence or give rise to a civil penalty under the Therapeutic Goods Act 1989:

- importing Sensaslim Solution into Australia
- exporting Sensaslim Solution from Australia
- manufacturing Sensaslim Solution in Australia
- supplying Sensaslim Solution in Australia.

Advertising Sensaslim Solution may also constitute an offence under the Act.

This cancellation is not related to the safety of the product. The product is not being recalled.

<http://www.tga.gov.au/newsroom/media-2011-sensaslim-111124.htm>

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However: 29th Nov, 2011

SensaSlim Why SensaSlim?

Selling and advertising of cancelled listed medicines: Questions and answers

"Where a product that has been cancelled from the ARTG, then depending on the circumstances, product that was available for retail supply at the time of cancellation may continue to be sold by retail (assuming the seller is not a "sponsor" or selling wholesale as described above).

However, any future introduction of product into the market (via import, or manufacture and supply) by a sponsor or wholesaler after the cancellation would, so long as the product is not included in the ARTG, be a breach of the Act."

<http://www.tga.gov.au/industry/cm-cancellations-cr-qa.htm>

SensaSlim, Solution Personal Care, 30 Day			
\$10.00	\$10.00	\$10.00	\$10.00



29/11/2011

<http://www.chemistdirect.com.au/sensaslim/>

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Meanwhile, others see the market opportunity



Have your cake....



...and eat it too

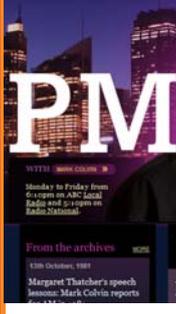
Claims:

- A biscuit or two could be undone with 1 pill.
- A tub of ice-cream may need 2 pills.
- And a Big Mac and fries will need 5 pills.

Xantrax, Fatblaster, Fatblaster Max, Fat Magnet, HungerBuster, Detox n Burn, Sensa, Undoit..

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Case Study: Undoit®



Timeline	
Feb 15, 2012	Undoit® complaint submitted to CRP & TGA
Apr 19, 2012	Undoit® complaint upheld by CRP
May 01, 2012	Undoit Plus® listed on ARTG
May 23, 2012	Original Undoit® listing cancelled by sponsor; TGA closed its review; Undoit Plus® promoted
May 30, 2012	ABC Radio interview: <i>Diet pill avoids sanctions by changing its name</i>
Jun 14, 2012	Undoit Plus® complaint submitted to CRP & TGA
Sept 6, 2012	CRP determination: Publication of a retraction, withdrawal of advertisement.
Dec 11, 2012	Undoit Plus® listing cancelled by TGA

Diet pill avoids sanctions by changing its name

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05/12/2011	Complaint to TGA
03/01/2012	SENSА® acknowledged as therapeutic good; referred to TGA Regulatory Compliance Unit and CRP Secretariat
27/11/2012	SENSА® agreed to pay \$800,000 in civil penalties for enforcement of consumer protection laws following action for false advertising claims by nine California district attorneys.
30/11/2012	SENSА® still promoting in Australia; no response from the TGA or CRP
17/05/2013	TGA notified complainant that SENSА® was declared a food by DoHV; food compliance issues being discussed.

See also: [Souvenaid®](#), a product promoted as a "medical food"

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Case Study: Berocca Performance®



Best launch of a consumer healthcare product
Winner: Bayer Australia, Berocca Performance Twist N Go launch campaign

Complaint No.	Date	Product	Complainant	Respondent
2010-10-017	17/02/11	Berocca Performance	Dr Ken Harvey	Bayer Australia Pty Ltd

Finding: Justified
Sections Found Justified: Code sections 4(1)(b), 4(2)(a), 4(2)(c)
Sections Found Not Justified: None
Action: Withdraw advertisement; withdraw representations
Recommendation to the Secretary: Yes

November, 2010

A creative and innovative concept with good implementation. It built on existing brand attributes and increased brand reach.

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Complaint: Berocca Performance®



- October, 2010 complaint submitted to CRP.
- February, 2011 CRP agreed that the claims Berocca® was clinically proven to have benefits in relation to concentration, tiredness, or stress, were unverified, likely to arouse unwarranted expectations, and misleading. Bayer requested to withdraw claims; they refused.
- May 2011 the CRP notified the Secretary (TGA) of Bayer's non-compliance with their request.
- March 8, 2013 the TGA finally upheld the CRP's determination and issued a regulation 9 "order" for compliance.
- Bayer then asked for a judicial review of the TGA decision in the Federal Court; that move was dismissed by consent with Bayer ordered to pay \$20,000 of the TGA's costs of the legal proceedings.
- Bayer has now asked Federal Health Minister for a review of the TGA decision. Meanwhile, the claims continue to be made.

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The evidence: Berocca Performance®



- The study initially cited was funded (and co-authored) by Roche from whom Bayer recently bought the rights to Berocca® (Psychopharmacology 2000;150(2): 220-225).
- It was a double-blind randomized-control trial, in which 80 healthy male volunteers, aged between 18 and 42 years, recruited from the U.K. University of Birmingham campus, were assigned to either Berocca or placebo.
- Questionnaires measuring psychological state were completed on day 1 (pre-treatment) and again on day 28 (post-treatment), following 28 days of treatment, which were administered at a dosage of one tablet daily.
- The perceived Stress Scale (PSS) was designed to assess the degree to which situations in people's lives are appraised as stressful and comprised 14 items, each scored on a 5-point Likert scale; total scores range from 0-56.

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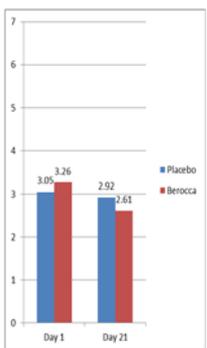
The evidence: Berocca Performance®



- In addition, participants were asked to rate, on a scale of 1 ("not at all") to 7 ("very"), to what extent they felt the following during the last 2 weeks: anxious; depressed; tense; tired; unable to concentrate.
- The authors reported that the Berocca® group had significantly lower levels of perceived stress than the placebo group on day 28.
- However, the results (from Table 2 in the paper) showed that the mean overall stress score (out of a possible 56) on day 1 and day 21 was 20.5 and 22.4 for the placebo group and 20.7 and 19.4 for the Berocca group. I disputed the statistical significance of these results given the large standard error of the mean.
- I also commented that the authors noted that any effect of Berocca® on tiredness failed to meet statistical significance (P=0.06).
- In addition, the statistical significance of the small difference in the results for concentration varied according to the test used and was unlikely to be of clinical significance.

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The evidence: Berocca Performance®

Day	Placebo	Berocca
Day 1	3.05	3.26
Day 21	2.92	2.64

- Figure 1.
 - Results to question, “were you unable to concentrate during the last two weeks?”
 - Scale 1 (“not at all”) to 7 (“very”)
- (Psychopharmacology 2000;150(2): 220-225).

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The evidence: Berocca Performance®



- Bayer then provided both the CRP and journalists with a more recent paper in support of these claims. (Psychopharmacology 2010; 211:55–68).
- Once again, this trial was supported and co-authored by the product sponsor.
- It was a randomised, placebo-controlled, double-blind, trial that assessed the cognitive and mood effects of a Berocca® in 215 males aged 30 to 55 years, who were in full-time employment in Newcastle on Tyne, U.K..
- Only a minority of the numerous tests performed showed a statistically significant result and even these differences were small and unlikely to be clinically significant.

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The evidence: Berocca Performance®



- The figures used in the paper showing allegedly statistically significant results were highly improper as they magnified the difference between the two arms of the trial by failing to show the zero baseline and the possible maximum results on the Y axis.
- It is well known that if enough tests are performed on a random group of subjects it is likely that some will cross the arbitrary boundary of statistical significance on a chance basis.
- It was also doubtful if any results obtained from vitamin and mineral supplementation in Birmingham and Newcastle on Tyne in the U.K. (two economically and socially deprived regions of the U.K) were relevant to the broader Australian population.
- While observational studies have frequently reported an association between cognitive function and nutrition, randomised trials of B group vitamins and antioxidant supplements have mostly found no beneficial effect, e.g. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1872030/>.

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“Clinically proven”

Therapeutic Products Advertising Complaints
COMPLAINTS RESOLUTION PANEL

- The Panel is concerned at the growing use of the words “clinically proven” in advertisements for therapeutic goods.
- Given the strength of this claim and the clear potential for it to mislead and deceive consumers, the Panel considers that its use in advertising should not even be contemplated unless unequivocally supported by robustly designed, published, peer-reviewed clinical trials which have been conducted upon the actual product being advertised or an identical formulation (as a minimum).
- Even where such evidence is available, the claim must also reflect the weight of all available evidence and not just the specific research being relied upon.

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Summary of problems



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

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Rules under review?



- A decade of government reports:
 - 2002 report of a “Review of Advertising Therapeutic Products in Australia and New Zealand”;
 - 2003 report of the “Expert Committee on Complementary Medicines in the Health System”;
 - Numerous discussion documents about a joint Australia-New Zealand trans-Tasman agency to regulate therapeutic products (suspended in 2007);
 - Australian Government. Improving advertising arrangements for therapeutic goods, 2010.
 - Australian National Audit Office. Therapeutic Goods Regulation: Complementary Medicines, 2011.
 - Australian Government. Review to improve transparency of the TGA, 2011.
 - Therapeutic Goods Administration, Informal Working Group on Complementary medicines Regulation, 2011-2012.

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Culminating in:



- Australian Government. TGA reforms: A blueprint for TGA's future, 2011. <http://www.tga.gov.au/about/tga-reforms-blueprint.htm>
- Australian Government. Delivering reforms - Implementation plan for TGA Reforms: A blueprint for TGA's future, 2012. <http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm>

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What did we want?

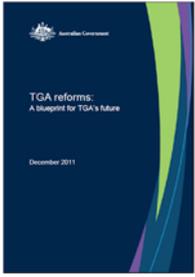


- A regulatory system with teeth!
- Mandatory labelling, "This product has **NOT** been evaluated by Australian Health Authorities to see if it works".
- Legislation for timely and meaningful sanctions for advertising violations (civil penalties, enforceable undertakings).
- Increased and better targeted post-marketing surveillance and transparent reporting of problems and cancellations.

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What did we get?

Over 4 years the TGA will:

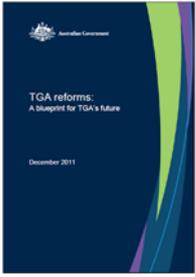


- Update and include in the regulations the TGA document, *Guidelines for the levels and kinds of evidence to support indications and claims* (two drafts have already been produced);
- Amend the Electronic Listing Facility (ELF) to provide increased guidance to sponsors and risk profile information to the TGA (to assist targeted reviews);
- Increase the number of coded indication in ELF to eliminate "creative" use of free text;
- Broaden pre-clearance requirements to include medical devices and advertisements on pay TV (but not the Internet);

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What did we get?

Over 4 years the TGA will:



- Provide more detailed and targeted post-marketing monitoring and reporting by the TGA;
- Create a central point at the TGA for all complaints about advertising, with the TGA to deal with those regarding efficacy or the intended purpose, not the Complaint Resolution Panel;
- Harmonise industry self-regulatory codes of conduct to support consistent ethical standards across the therapeutic goods industry;
- Improve labelling to assist consumers make informed choices;
- Explore enhanced sanctions and penalties for regulatory violations including advertising breaches.

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In conclusion: we are not happy!



- We will continue to:
 - Submit more complaints;
 - Publicise system problems through the media;
 - Put in submissions to government and industry inquiries;
 - Agitate on industry and government working groups;
- Until the system improves.
- Join us!

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