



Therapeutic Goods Advertising Code Council

Annual Report
1 July 2011 – 30 June 2012

Introduction

The Therapeutic Goods Advertising Code Council (TGACC) is established by regulation 42A of the Therapeutic Goods Regulations 1990 (the Regulations) and its functions (as set out in regulation 42B) are as follows:

- (1)
 - (a) to consider requirements for the advertising of therapeutic goods and changes to the Therapeutic Goods Advertising Code, to accept submissions for this purpose and to advise the Minister accordingly; and
 - (b) to make recommendations to the Minister for achieving greater uniformity in approval processes and standards for advertising therapeutic goods in specified media and broadcast media; and
 - (c) to make recommendations to the Minister about requests for review of a decision of the Secretary under regulation 5G; and
 - (d) to consider matters raised at Council meetings by Council members or observers to the Council and advise the Minister accordingly; and
 - (e) to advise the Minister on any matter referred to the Council by the Minister or Secretary; and
 - (f) any other function conferred on the Council by the Regulations.

- (2) The Council may, with the approval of the Minister, appoint sub-committees of its members to inquire into, and report on, any matter that is within the functions of the Council.

Regulation 42Q of the Regulations requires the TGACC, within three months after the end of the financial year, to provide the Minister a written report on the operation of the Council for that financial year.

Five meetings were held during the financial year 2011/2012:

- 3 August 2011
- 13 October 2011 (teleconference);
- 7 December 2011;
- 1 February 2012;
- 4 April 2012 (teleconference); and
- 6 June 2012.

Ms Jenny Hefford, Chief Regulatory Officer, Therapeutic Goods Administration (TGA), was in the Chair for this reporting period.

The TGACC is broadly representative of all major therapeutic goods advertising stakeholder groups, including the therapeutic goods and advertising industries, media, consumers, healthcare professionals and government. The TGACC membership for 2011/2012 is listed at [Appendix 1](#). The Secretariat is provided by the Australian Self-Medication Industry (ASMI) under contract to the TGA.

The contract for the provision of Secretariat services for the TGACC and Complaints Resolution Panel (CRP) was awarded to the ASMI in December 2010

for a period of 18 months with an option to extend for a further 18 months following an open tender process.

Important issues considered by the Council

The implementation of several recommendations for amendment to the Therapeutic Goods Advertising Code (the Advertising Code) made over the previous five years has been delayed again by the TGA's ongoing reform process. The release of "*Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future*" in July 2012 should see the proposed reforms to the advertising framework progressed separately from the recommended amendments to the Advertising Code.

Advertising reform process

Throughout the past year the TGA has been continuing to develop proposals for the following key areas:

1. The pre-approval process
2. Complaints handling
3. Penalties and sanctions

Of relevance to the operation of the TGACC and the CRP was the report of the Transparency Review Panel, *Review to improve the transparency of the Therapeutic Goods Administration*, which was released in July 2011. Generally, members supported the notion of increased transparency while recognising the need to address the balance between the public right-to-know with commercial and professional sensitivities, and the implications for public health messaging.

Further, the release of "*TGA reforms: A blueprint for TGA's future*" ("the TGA blueprint") in December 2011 also impacted on the advertising reform process. Five recommendations for reform of the advertising arrangements had been accepted and this is expected to result in changes to the advertising legislative framework following consultation with stakeholders. The following were of particular interest to the TGACC:

- A proposal for the introduction of a pre-approvals process for medical devices advertising (in response to an increase in the number complaints about such advertising) and broadening the coverage of pre-approvals to include pay-television;
- A proposal for single point of entry for all complaints to allow an administrative process of triaging by the TGA with advertisements that pose a significant risk to public health or involve claims of about the efficacy of the product being handled by the TGA.
- Appropriate sanctions and penalties in relation to powers currently available to the ACCC and other government departments are to be considered by the TGA, following which there will be another consultation round before implementing proposed amendments; and

- Matters of confidentiality and conflicts of interest were given serious consideration in the context of the transparency review and will guide the implementation of its recommendations.

The report “Advertising regulatory framework – Options for reform”, containing outcomes of the TGA internal reviews on the three key areas: the pre-approval process, complaints handling and the range of sanctions and penalties available for advertising breaches, was published on the TGA website at the end of May 2012. A consultation paper for future advertising arrangements is proposed to be developed based on the options and recommendations within this document.

Summary of recommendations for amendment to the Therapeutic Goods Act 1989 (the Act), Therapeutic Goods Regulations 1990 (the Regulations) and the Therapeutic Goods Advertising Code (the Code)

There have been no further recommendations made by the TGACC for amendment to the Act, Regulations or Code.

- 1) The TGACC noted the revised ‘Disclosure of interest provisions under regulation 42N of the Therapeutic Goods Regulations 1990, which came into effect on 22 June 2011, whereby “pecuniary interest” was replaced by “material personal interest (whether pecuniary or not)”.
- 2) An amendment to Regulation 5Q of the Regulations to clarify that the Secretary can delegate to the ASMI and CHC all advertising pre-approval functions (i.e. to approve, refuse to approve, vary the approval and to set conditions on any approval) commenced on 9 December 2011.
- 3) The CRP was pleased to see that changes to the Regulations had come into effect with the making of the Therapeutic Goods Amendment Regulations 2012 (No 142) on 28 June 2012, amending Regulation 42ZCAJ to enable the CRP, under certain circumstances, to consider complaints where the subject matter of a complaint may be before a court after a complaint has been received by the Panel. The CRP also supported an amendment to Regulation 42ZCAA to provide clarity that “another authority” includes the Therapeutic Goods Administration, thus removing any doubt that the TGA is an authority to which the Panel can send complaints in accordance with regulation 42ZCAGA.

TGACC working group

A working group, comprising the Advertising Services Managers (ASMs), the TGA representative and the TGACC executive officer, was formed in April 2011 to consider matters of interpretation and consistency of approach between the ASMs.

The working group continued to work on the following areas:

1. Paragraph 4(2)(g) of the Code in relation to money-back guarantees. (paragraph 4(2)(g) requires that advertisements must not claim that the advertised product is magical or infallible or that it is a guaranteed or sure cure). The ASMs developed an agreed approach to the application of this

section of the Code, which did not entail any recommended change to the Code;

2. Section 4(7) of the Code, Testimonials. The documentation required by the ASMI and CHC ASMs has differed, even though they are exercising the same delegation. Some members held the view that as there was no legal basis for statutory declarations, they should not be required for testimonials forming part of an advertisement. Most members were of the view that for clarity and consistency of decision-making the provision of statutory declarations should be required a part of any submission seeking approval of an advertisement in which testimonials form part of the advertisement;
3. Section 4(8) of the Code in relation to the advertising of an offer of a sample (section 4(8) requires that advertisements must not offer samples of therapeutic goods) Following consideration of this section of the Code, the working group recommended its retention, on the basis that advertising an offer of a sample of a therapeutic good is inappropriate unless it has been initiated by a healthcare profession. The TGACC accepted the recommendation;
4. The requirement in Regulation 5G is that an approval officer must be satisfied that the advertisement complies with the Code, in relation to the substantiation of therapeutic claims. The working group developed an agreed common approach to the evaluation of evidence which was accepted by the TGACC; and
5. Restricted representations as coded indications. The CRP had received a small number of complaints in which the issue of there being no basis in the legislation to make restricted representations without formal approval for their use (per subsection 42DL(1) of the Act) had been raised. As there has been a long-held practice of advertising restricted representations included in coded indications for some listed complementary products, the TGACC recommended that this issue be dealt with quickly and expeditiously by the Office of Complementary Medicines.

Following the work of the TGACC working group, regular meetings of the ASMs and the TGA (monthly) have been reinstated.

Applications for the use of a restricted representation (s.42DE of the *Therapeutic Goods Act 1989* refers)

A restricted representation is a reference, expressly or by implication, to forms of diseases, conditions, ailments or defects which are generally accepted to be:

- not appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional; and/or
- beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

During 2011/2012, the TGACC considered a number of applications from sponsors seeking permission to use “restricted representations” in advertisements for therapeutic goods directed to consumers. These applications are listed at [Appendix 2](#).

Review of a decision of the Secretary’s delegate to refuse to approve an advertisement

Where the Secretary’s delegate (appointed by either the Australian Self-Medication Industry or the Complementary Healthcare Council of Australia) refuses to approve an advertisement under Regulation 5G, the sponsor is able to seek a review of this decision by the Minister (or Minister’s delegate) under Regulation 5M. Regulation 5M also requires the Minister to take into account any recommendation made by the TGACC or the CRP.

The Minister for Health and Ageing received two such appeals despite the many hundred of advertisements considered by the delegates in the course of a year ([Appendix 3](#)).

The TGACC considered these appeals and provided advice to the Minister (or delegate) in relation to the subject matters.

Prior to making a decision in relation to the appeals, the Minister’s delegate considered these recommendations made by the TGACC in line with the requirements of the Regulations.

Education and Communication

Seminars

Nine “Fundamentals” and three “Advanced” advertising training seminars were held during the 2011/2012 financial year: Fundamental seminars - three in Sydney, two in Melbourne, two in Brisbane and one each in Adelaide and Perth; Advanced seminars – two in Sydney and one in Melbourne. The success of these seminars is underlined by the fact that, of the stakeholders attending these comprehensive seminars on the current requirements, more than 90% of evaluation responses have indicated that the program, presentation quality and the presenters were good and/or excellent. A total of 385 persons from the therapeutic goods industry, publishers and health professionals attended the seminars held over the year.

The seminars were presented by:

- Advertising Services Managers (ASMs) from the Australian Self-Medication Industry and Complementary Healthcare Council of Australia;
- Director of the Recalls and Advertising Section, and the Manager of the Advertising Unit, TGA; and
- Executive Officer of the TGACC and CRP.

New members of the TGACC are invited to attend the Fundamentals seminar.

Reports given by the Complaints Resolution Panel at TGACC meetings

Mr Jason Korke was appointed the Chairman of the CRP from 3 February 2012 for a fourth two-year term of office.

The Chairman presented a report relating to the CRP operations to the TGACC at each of its meetings.

Increasing number and complexity of complaints

The increase of 30.7% in the number of complaints received by the CRP in the 2011/2012 financial year presented more significant challenges for the timeframe for their consideration and determination.

In January 2012, the Executive Director, ASMI, the Head of the Office of Product Review, the Director of the Recalls and Advertising Section of the TGA, the Advertising Projects Officer, TGA, and the TGACC/CRP Executive Officer met to review the complaints handling processes, operational efficiencies and resourcing matters.

A number of administrative proposals for streamlining the complaints handling processes that had been implemented at the beginning of 2011 were recognised as having been effective in speeding up complaint handling (refer [Appendix 4](#)), although the continuing increase in the number of complaints received each month and their increasing complexity was a challenge. To address this, the TGA funded an additional seven teleconferences to the schedule of CRP meetings, for a total of 12 face to face and 13 teleconference meetings between 1 July 2011 and June 2012. As well, the TGA has funded an additional administrative support position for the TGACC/CRP Secretariat from December 2011.

Issues noted by the CRP and TGACC as a result of the consideration of complaints

1. The transparency of complaint processes subsequent to the CRP determination has been enhanced by the publication by the TGA of Regulation 9 Orders on the TGA website.
2. The CRP was involved in a Federal Court proceeding with an advertiser about process issues with respect to the Panel's determination for two complaints. The judge referred the matter back to the Panel for reconsideration.
3. The proportion of complaints about listed medical devices has increased from 22% in 2008 to 43.3% in the 2011 calendar year.
4. The continuing increase in advertisements found to contain misleading representations commonly relate to the failure of advertisers to substantiate

the efficacy claims made in their advertising (a breach of section 4(1)(b), 4(2)(a), 4(2)(c), 4(4) or 4(5) of the Advertising Code).

5. The continuing high number of advertisements found to contain prohibited and/or restricted representations (i.e. representations about serious diseases, conditions or disorders) (a breach of section 5(1) or 5(2) of the Advertising Code).
6. Internet advertising complaints now account for 73.5% of all complaints determined;
7. The number of complaints about advertisements in broadcast media is lower than those for print media and the internet. However, this difference may reflect the transitory nature of broadcast advertising and the additional difficulty for the complainant in documenting such a complaint; and
8. The number of complaints about the advertising of listed medical devices and the advertising of complementary medicines comprise the predominant categories about which complaints are made.

A summary of complaints considered by the CRP in the 2011/2012 financial year and trend data for the years 2007-2012 (up to 30 June) is at [Appendix 4](#).

Websites and the Central Complaints Mail Box

The website www.tgacc.com.au went live in 2000 and continues to be an invaluable resource for interested parties in Australia and internationally.

The CRP website www.tgacrp.com.au provides ease of access to the complaints system for those who have difficulty in understanding the complexities of the system, in particular consumers and, as well, other stakeholders. Links to reports on the complaints considered by the CRP are published on the home page.

Education and the determinations of the Panel

As the determinations of the Panel are in the public domain and published on the CRP website, the provision of actual examples in training seminars gives quality and relevance to the training.

Conclusion:

The normal responsibilities of the TGACC were executed in accordance with the regulations.

Jenny Hefford
Chairman

TGACC Representatives 2012

Chairman: Jenny Hefford, Chief Regulatory Officer, TGA

Members

Manufacturer/Supplier Representatives
Australian Self-Medication Industry
Complementary Healthcare Council
Australian Direct Marketing Association
Direct Selling Association of Australia
Medical Technology Association of Australia
Advertising Industry Representatives
Australian Association of National Advertisers
Communications Council
Consumer Representatives
Australian Consumers' Association
Consumers' Health Forum
Healthcare Professional Representatives
Australian Traditional Medicines Society
Pharmacy Guild of Australia and Pharmaceutical Society of Australia
Royal Australian College of General Practitioners
Media Representative
Publishers' Advertising Advisory Bureau
Government Representative
Therapeutic Goods Administration

Observers

Accord
Australian Competition and Consumer Commission
Australian Pharmaceutical Manufacturers' Association
Complaints Resolution Panel Chair
Media – Broadcast – FreeTV Australia
Medsafe New Zealand

Experts/guests

Advertising Services Manager, ASMI

**APPLICATIONS FOR APPROVAL TO USE A RESTRICTED REPRESENTATION
(*Therapeutic Goods Act 1989*, section 42DF)**

Prior to making a decision, the Act (s 42DF) requires the Secretary of the Department of Health and Ageing (or delegate) to consider any recommendation made by the TGACC about the applications received. After its consideration of the submissions in terms of the public interest criteria that are set out in the TGAC, the Council put forward recommendations to the Secretary's delegate in relation to the following:

Clinical Laboratories Pty Ltd

Healthscope Collection Kit

Inverness Medical Innovations Australia Pty Ltd

Cholestech SDX System, Triage System, Clearview D-Dimer

SSL Australia Pty Ltd

Scholl Blister/Shield Plaster and Scholl Corn Blister/Shield Plaster

Procter & Gamble Pty Ltd

Vicks products

Johnson & Johnson Medical Pty Ltd

One Touch Verio Blood Glucose Monitoring System

Specsavers Pty Ltd

Specsavers contact lens, vision corrective, tinted, single use

Vasyli Medical Asia Pacific Pty LTD

Dr Comfort Footwear

Covidien Pty Ltd

Surgipack BioMasks

Reckitt Benckiser

Scholl Cushion

Novo Nordisk

Sterile hypodermic needles

**REVIEWS OF A DECISION TO REFUSE TO APPROVE A BROADCAST MEDIA
ADVERTISEMENT (Therapeutic Goods Regulations 1990, regulation 5M)**

- 1. Pharmacare Laboratories Pty Ltd**
Promensil Double Strength (AUST L 154447)

- 2. Phytologic Pty Ltd**
Blooms Memorex IQ and Memory Boost (AUST L 189905)

**COMPLAINTS RESOLUTION PANEL
SUMMARY OF COMPLAINTS FOR THE FINANCIAL YEAR
1 JULY 2011 – 30 JUNE 2012**

Total number of complaints received = 405 (30.7% increase)
(310 in 2010/2011)

Total number of complaints determined by the Panel = 373 (13.4% increase)
(329 in 2010/2011)

Number of meetings = 21 including 9 teleconferences (21 in 2010/2011)

Complaints determined by the Panel

Category of product	Number	% of total determined (373)
Complementary	170	45.6%
Cosmetic	2	0.5%
Device	159	42.6%
OTC	5	1.3%
Food	7	1.9%
S4	22	5.9%
Other	8	2.1%

Method of provision of the complaint

Letter	94	25.2%
Email	272	72.9%
Fax	7	1.9%

Type of complainant

Anonymous	81	21.7%
Requested Anonymity	237	63.5%
Known	55	14.7%

Media in which the complaint appeared

Note: Some complaints appear in more than one medium

Print	73	19.6%
Broadcast	23	6.2%
Internet	274	73.5%
Other	19	5.1%

Findings of the Panel

Not Justified	4	1.1%
Justified		
including 2 with no sanction, undertakings accepted	251	67.3%
Treated as Withdrawn	118	31.6%

Total Determined

373

Requests made by the Panel		% of total found justified (251)
Withdrawal of Ad	249	99.2%
Withdrawal of Rep	235	93.6%
Retraction requested	66	26.3%
No Sanction	2	0.8%

Complaints Treated as Withdrawn

	<u>Number</u>	<u>% of total TAW (118)</u>
Withdrawn 42ZCAF (a) Misconceived etc	69	58.5%
Withdrawn 42ZCAF (b) Previously dealt with by the Panel	19	16.1%
Withdrawn 42ZCAF(c) Another authority	0	0.0%
Withdrawn 42ZCAF (d)(i) Withdrawn by the Complainant	1	0.8%
Referred to NICNAS	2	1.7%
Referred to State Food Authority	5	4.2%
Referred to ASMI	0	0.0%
Referred to CHC	4	3.4%
Referred to TGA	38	32.2%
Referred to Other Body	1	0.8%
Total Treated as Withdrawn	<u>118</u>	

Note: Some TAW complaints have been recorded in more than one category (such as Withdrawn 42ZCAF (a) Misconceived AND Referred to TGA)

Recommendation to Secretary	56
Referred to Regulatory Compliance Unit	124

Timeframes

<i>Averages (note: the averages cannot be summed!)</i>	<u>Calendar days</u>	<i>2010/2011 financial year</i>
Days from receipt to Panel	87	108
Days from Panel to determination sent	73	49
Days from receipt to determination sent	135	123

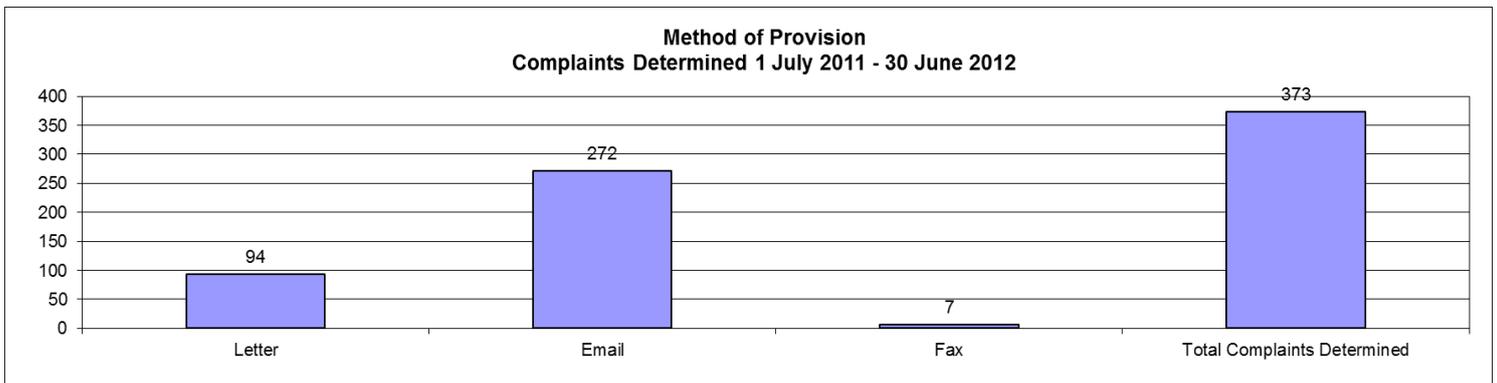
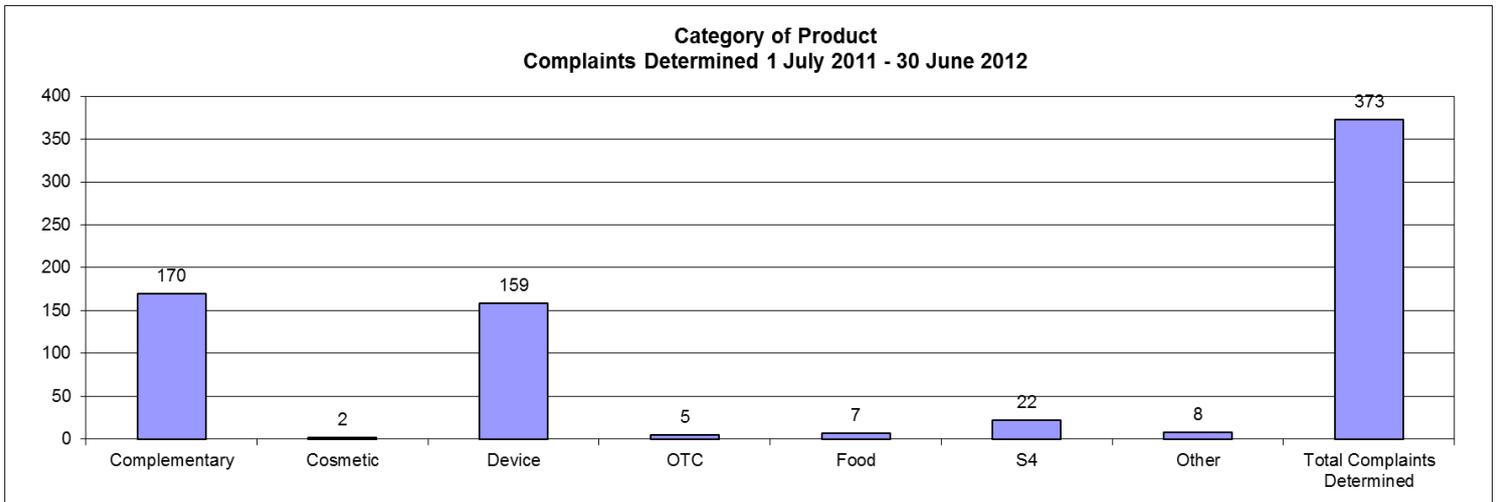
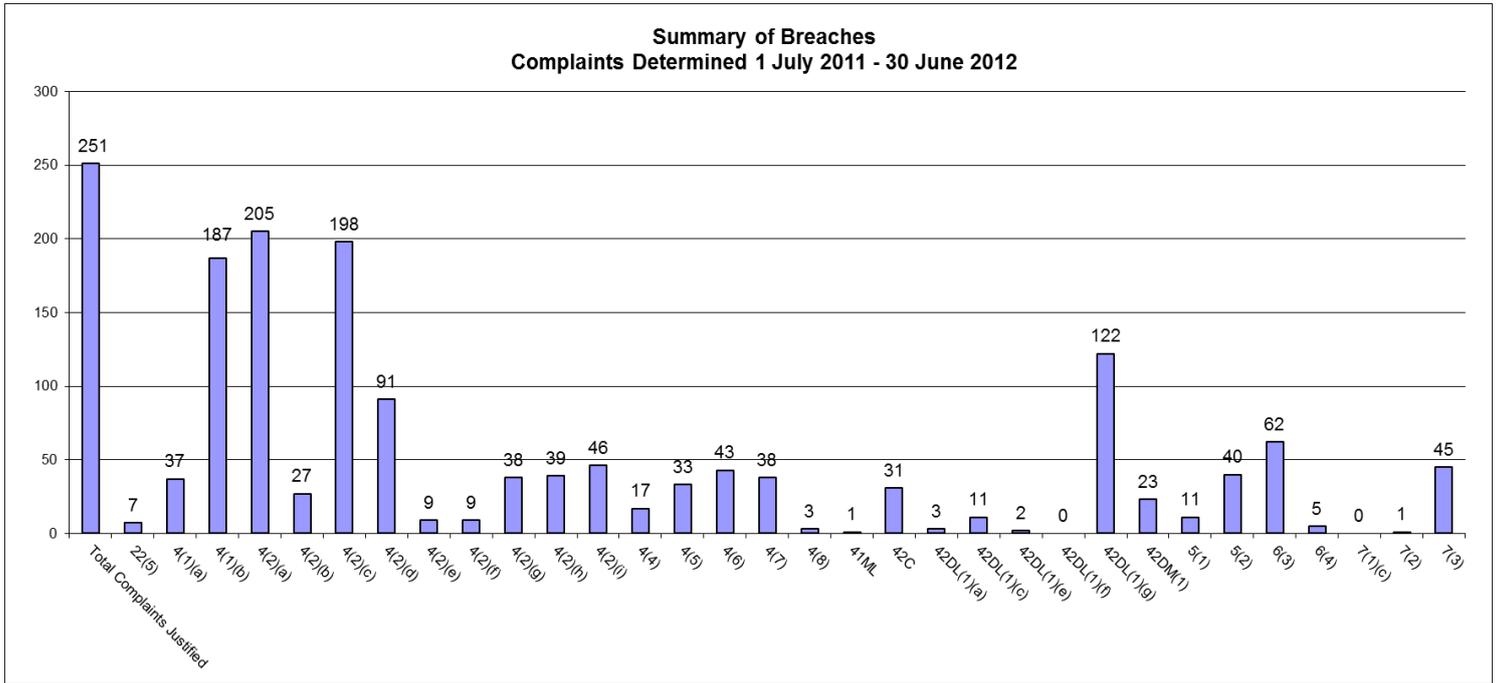
Summary of breaches

Act	Number Justified	% of total found justified (251)
22(5)	7	2.8%
41ML	1	0.4%
42C	31	12.4%
42DL(1)(a)	3	1.2%
42DL(1)(c)	11	4.4%
42DL(1)(e)	2	0.8%
42DL(1)(f)	0	0.0%
42DL(1)(g)	122	48.6%
42DM(1)	23	9.2%

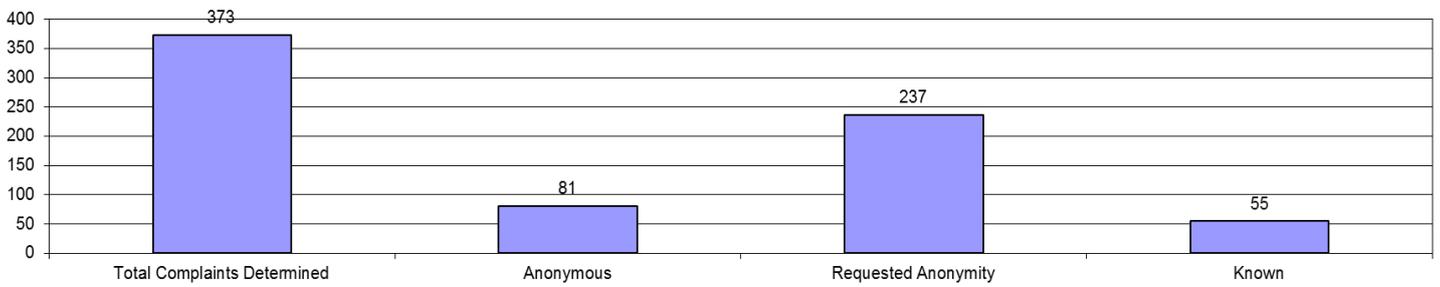
Code	Number Justified	% of total found justified (251)
4(1)(a)	37	14.7%
4(1)(b)	187	74.5%
4(2)(a)	205	81.7%
4(2)(b)	27	10.8%
4(2)(c)	198	78.9%
4(2)(d)	91	36.3%
4(2)(e)	9	3.6%
4(2)(f)	9	3.6%
4(2)(g)	38	15.1%
4(2)(h)	39	15.5%
4(2)(i)	46	18.3%
4(4)	17	6.8%
4(5)	33	13.1%
4(6)	43	17.1%
4(7)	38	15.1%
4(8)	3	1.2%
5(1)	11	4.4%
5(2)	40	15.9%
6(3)	62	24.7%
6(4)	5	2.0%
7(1)(c)	0	0.0%
7(2)	1	0.4%
7(3)	45	17.9%

Total number of breaches	1,384
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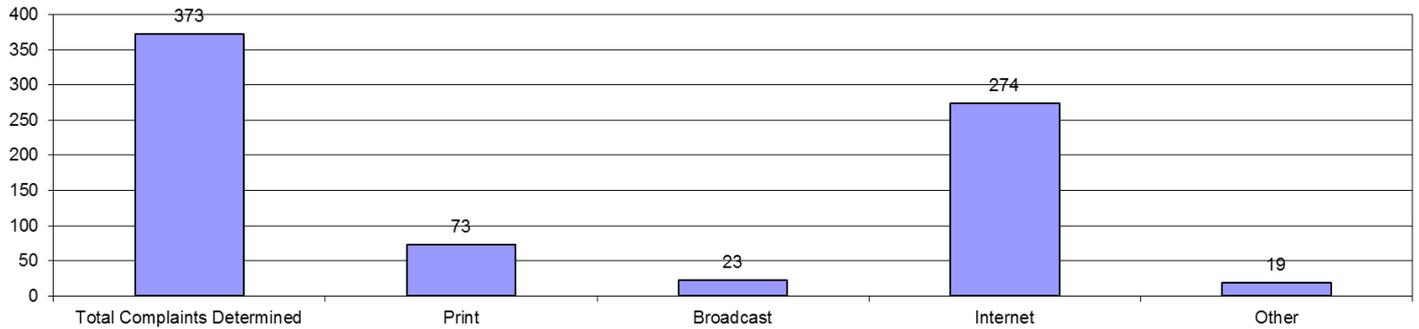
Graphical Representations of Complaints Summary 1 July 2011 – 30 June 2012



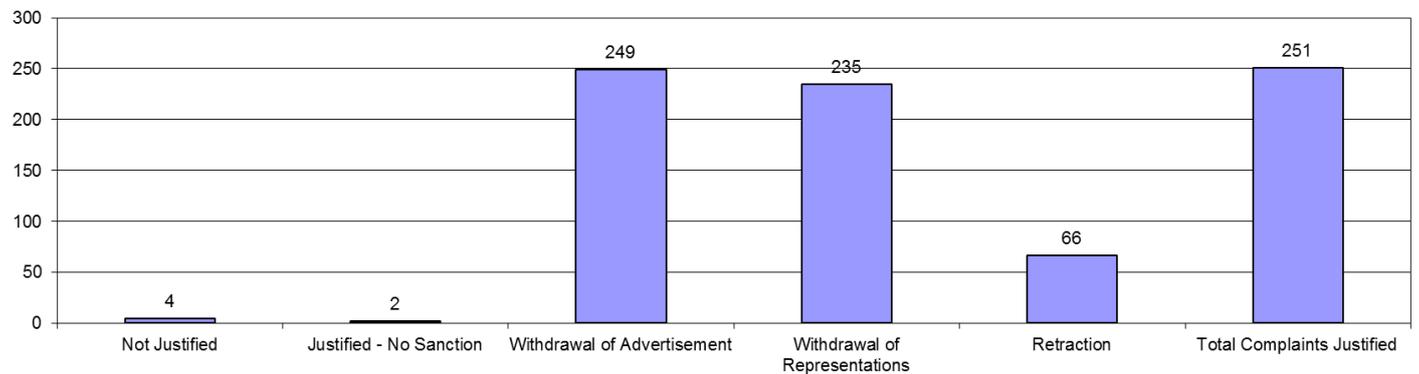
Type of Complainant
Complaints Determined 1 July 2011 - 30 June 2012



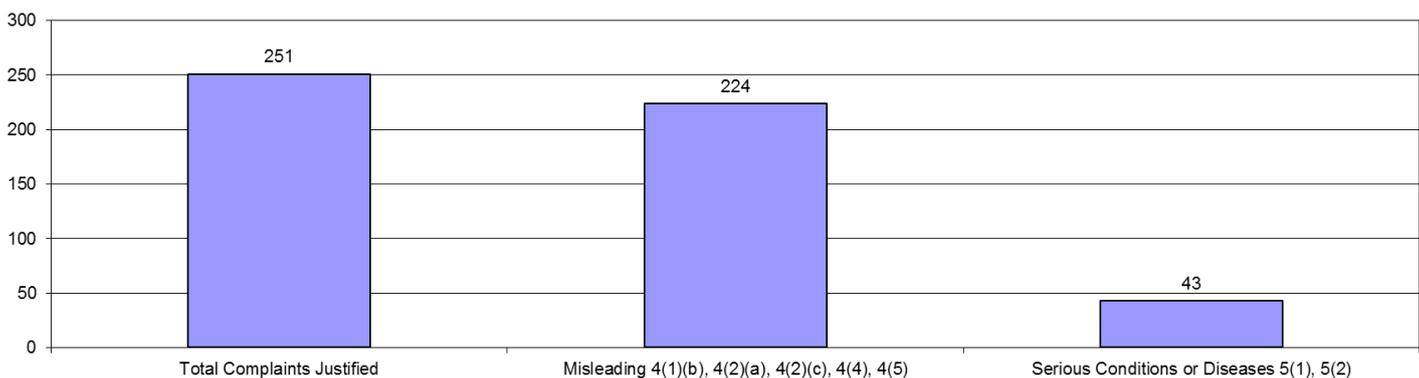
Media in which the complaint appeared
Complaints Determined 1 July 2011 - 30 June 2012
Note: some advertisements appear in more than one medium



Findings of the Panel and Sanctions
Complaints Determined 1 July 2011 - 30 June 2012

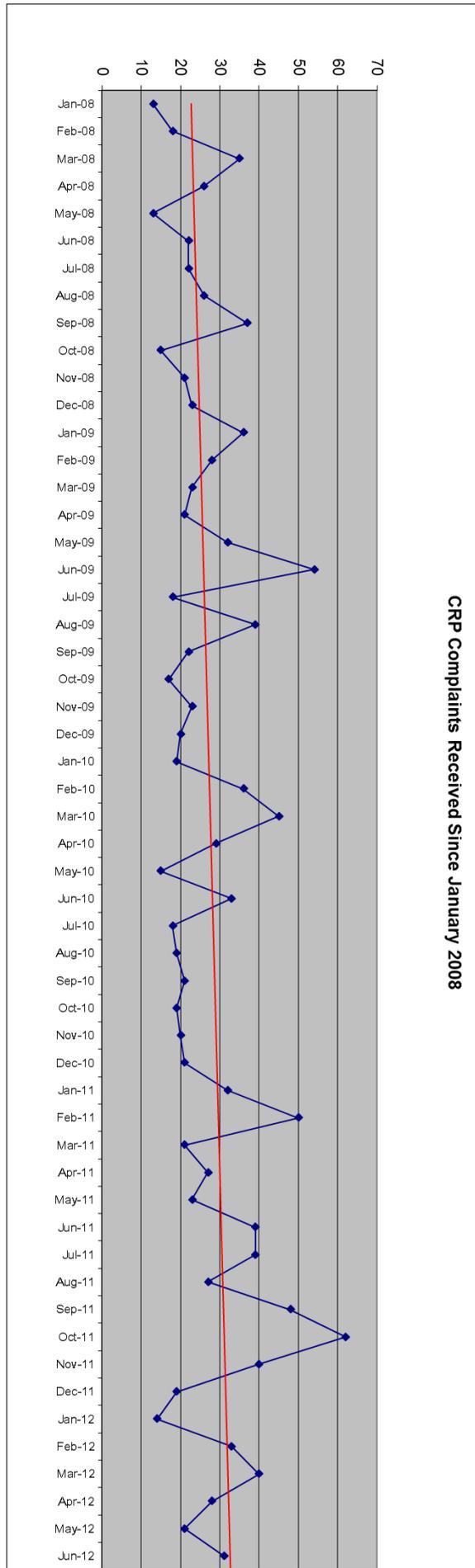


Justified complaints which were found to be misleading OR refer to serious conditions/diseases
Complaints Determined 1 July 2011 - 30 June 2012

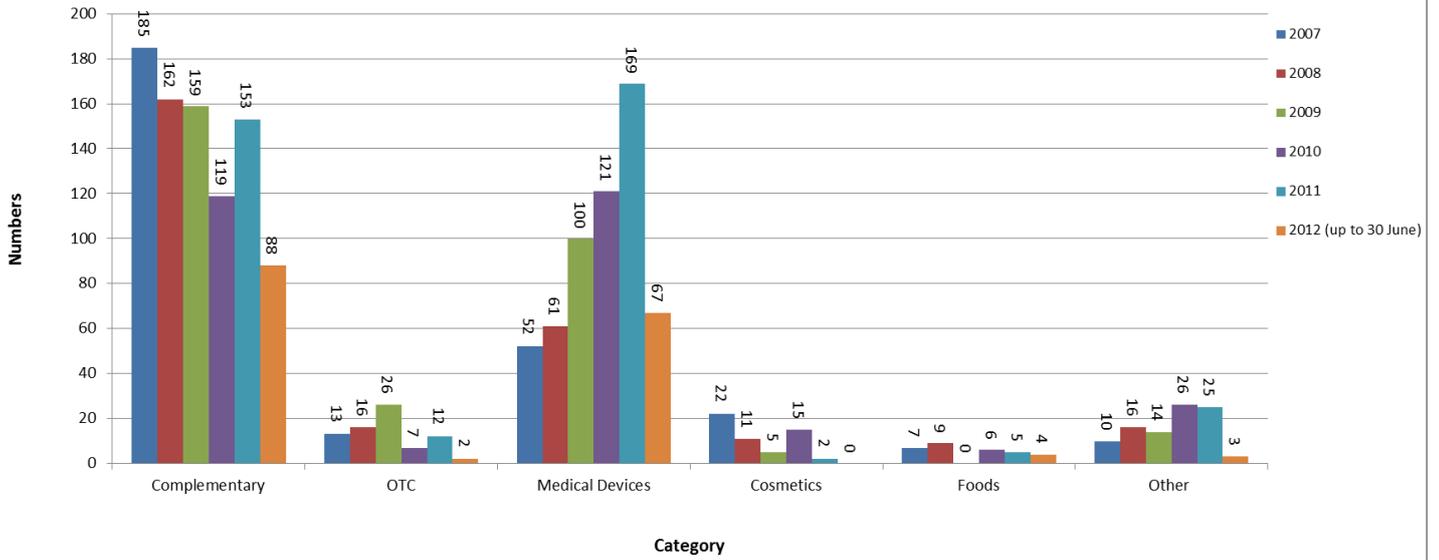


Justified complaints which breach at least one of these Code sections

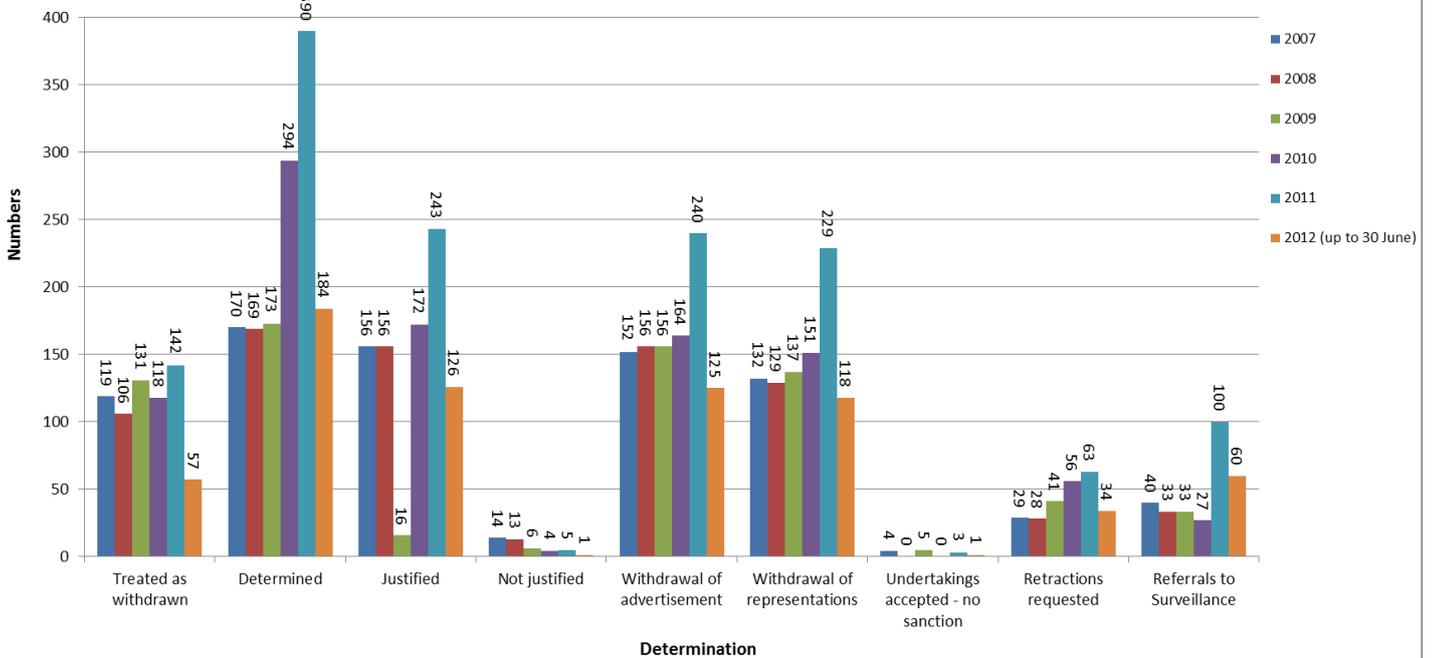
Trends



**Complaint Trends By Category
2007 - 2012 (up to 30 June)**



**Complaint Trends by Determination
2007 - 2012 (up to 30 June)**



Complaint Processing Timeframes 2007 - 2012 (up to 30 June)

