



Therapeutic Goods Advertising Code Council

Annual Report
1 July 2012 – 30 June 2013

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.

Four meetings were held during the financial year 2012/2013:

- 1 August 2012 (teleconference)
- 5 December 2012 (teleconference);
- 3 April 2013 (teleconference); and
- 18 June 2013 (face-to-face).

Ms Jenny Hefford, Chief Regulatory Officer, Therapeutic Goods Administration (TGA), was in the Chair for the August 2012 meeting and Dr Larry Kelly was appointed by the Council at the meeting held on 5 December 2012 and continues in that role.

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 2012/2013 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 following an open tender process, for a period of 18 months with an option to

extend for a further 18 months. At the end of June 2012, the contract was extended to 31 December 2013.

Important issues considered by the Council

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 2007 (the Advertising Code)

There have been no recommendations made by the TGACC for amendment to the Act, Regulations or Code in the year 1 July 2012 to 30 June 2013.

However, the implementation of several previous Council recommendations for amendment to the Advertising Code has been delayed by the TGA's ongoing reform process to the advertising requirements for therapeutic goods. The release of "*Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future*" in July 2012 was followed by the release of a Consultation Regulation Impact Statement in May 2013 entitled "Regulating the advertising of therapeutic goods to the general public".

Advertising reform process

The TGA has developed proposals for the following key areas:

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

The following items from the "*TGA reforms: A blueprint for TGA's future*" (released in November 2011) were of particular interest to the TGACC and were carried forward to the Consultation Regulation Impact Statement (published 31 May 2013) following their appearance on the TGA website at the end of May 2012 in the report "Advertising regulatory framework – Options for reform". These were presented as outcomes of the TGA internal reviews on three key areas: the pre-approval process, complaints handling and the range of sanctions and penalties available for advertising breaches.

- 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.

The Advertising Services Managers (ASMs) and the TGA

The TGACC working group that had been established in April 2011 was replaced in 2012 by regular monthly meetings of the ASMs and the TGA. The group is chaired by the TGA, and attended by the ASMI and the Complementary Healthcare Council (CHC) as delegates of the Secretary of the Department of Health and Ageing.

The objective of the group is to improve the timeliness and consistency of decision making for the approval of advertising of designated therapeutic goods before those advertisements are broadcast or published in specified media. To this end during 2012/13 the group has been developing:

- an improved and revised approval application form and accompanying instructions for the form to assist advertisers
- a series of information papers to assist the approvals officers (ASMs) to identify potentially relevant information when making decisions.

The group has met 9 times during the current year.

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.

Prior to making a decision under the Act (s 42DF), the Secretary of the Department of Health and Ageing (or delegate) must take into account any recommendation made by the TGACC about the applications received.

During 2012/2013, the TGACC provided recommendations to the Secretary of the Department of Health and Ageing on four applications seeking permission to use “restricted representations” in advertisements for therapeutic goods directed to consumers.

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

Where the Secretary’s delegate in either ASMI or the CHC refuses to approve an advertisement under Regulation 5G, the sponsor is able to seek a review of this decision by the Minister (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 received one such appeal only (Appendix 3), despite the many hundreds of advertisements considered by the delegates in the course of a year.

The TGACC made one recommendation to the Minister.

Education and Communication

Seminars

Nine “Fundamentals” and four “Advanced” advertising training seminars were held, with the assistance of funding from the TGA, during the 2012/2013 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, one in Melbourne and one in Canberra for the TGA. The continuing success of these seminars is apparent from 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 361 persons from the therapeutic goods industry, publishers and health professionals registered to attend the seminars held over the year. In addition approximately 30 TGA and ACCC staff attended a seminar held at the TGA in February 2013.

The seminars were presented by:

- Advertising Services Managers (ASMs) from the ASMI and CHC;
- Director of the Recalls and Advertising Section, the Manager of the Advertising Unit, TGA; and
- Executive Officer of the TGACC and CRP.

As well, new members of the TGACC and the CRP, consumer representatives, and other complaints panels’ staff have attended the Fundamentals seminar.

Reports given by the Complaints Resolution Panel at TGACC meetings

Mr Jason Korke continued as the Chairman of the CRP. His fourth two-year term of office ends in February 2014.

The current year saw the departure of some long-serving Panel members, including those nominated by Choice (Lawson Lobb – 7 years), Consumers’ Health Forum (Judith Maher – 8 years) and ASMI (Steven Scarff – 3 years). All gave most generously of their time and invaluable expertise throughout their term of office.

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

Decreasing number and increasing complexity of complaints

Despite a considerable decrease in the number of complaints received by the CRP in the 2012/2013 financial year (26%), the increase in the complexity of the complaints continues to present significant challenges for the timeframe for their consideration and determination.

In March 2012, the Federal Court considered issues raised by Swisse about the Panel's determination for two complaints. The Court referred the matter back to the Panel for reconsideration. A reconstituted Panel was formed which did not include any member present for the previous consideration of the Swisse complaints. Three meetings were held of the reconstituted CRP. After consideration by the reconstituted panel, the determination was finalised and provided to the advertiser on 4 June 2013 followed by publication on the CRP website on 21 June 2013 at: http://www.tgacrp.com.au/uploaded/doc/Swisse_Products.pdf .

A number of administrative processes now have been introduced by the CRP to improve complaint handling. These include a revised, comprehensive letter seeking a response to a complaint, in which the Panel (per regulation 42ZCAH) may raise matters other than those that have been identified by the complainant; the introduction of guidelines for the provision of evidence in support of advertising claims; and the introduction of a response form to establish the accurate identity of the person responsible for an advertisement that is the subject of a complaint.

The CRP procedures document has been updated to:

1. give clarity as to the Panel's role and *modus operandi*;
2. give the material a more logical flow; and
3. introduce a new section on recommendations made to the Secretary following failure to comply fully with requests made by the Panel of an advertiser in a determination.

There were a total of 12 face-to-face and 9 teleconference meetings between 1 July 2012 and 30 June 2013. An additional full-time administrative support position for the TGACC/CRP Secretariat was appointed from June 2012.

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

1. Most advertisements are found to contain misleading representations (approximately 75%) and 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) and/or 4(5) of the Advertising Code).
2. The continuing high number (about 30%) 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).
3. In this year, internet advertising complaints account for 69.7% of all complaints determined;
4. 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 2012/2013 financial year for the years 2011-2013 (up to 30 June) is at [Appendix 2](#).

Websites and the Central Complaints Mail Box

The website www.tgacc.com.au went live in 2000 and, although now in need of updating, continues to be available as a useful resource.

The CRP website www.tgacrp.com.au provides access to the complaints system for consumers and other stakeholders. Links to reports on the complaints considered by the CRP are published on the home page.

Final determinations of the Panel are published in full at www.tgacrp.com.au/complaints. By doing so, the Panel affords transparency, in terms of complaints considerations, and provides a valuable resource for all those involved in the advertising of therapeutic goods to consumers.

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

Larry Kelly
Chairman

TGACC Representatives 2013

Chairman: Dr Larry Kelly, Head, Monitoring and Compliance Group, 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 Medicine 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 Australasia Ltd
Australian Competition and Consumer Commission
Australian Pharmaceutical Manufacturers' Association
Complaints Resolution Panel Chair
Media – Broadcast – FreeTV Australia
Medsafe New Zealand

Guests

Advertising Services Manager, ASMI

**COMPLAINTS RESOLUTION PANEL
SUMMARY OF COMPLAINTS FOR THE FINANCIAL YEAR
1 JULY 2012 – 30 JUNE 2013**

Total number of complaints received = 298

(405 in 2011/2012 – 26% decrease)

Number of complaints determined* by the Complaints Resolution Panel = 211

**Finalised with determination sent (including complaints treated as withdrawn (TAW) per regulation 42ZCAF)*

Note: Complaints 'Not within Jurisdiction' were previously included in this figure but will now be reported separately; therefore a percentage change cannot be included

Number of complaints 'Not within Jurisdiction' = 86

Total complaints dealt with by the Complaints Resolution Panel = 297

Number of meetings = 21 including 9 teleconferences (21 in 2011/2012)

Complaints dealt with by the Complaints Resolution Panel

Category of product	Number	% of total (297)
Complementary	130	43.8%
Cosmetic	5	1.7%
Device	81	27.3%
OTC	6	2.0%
Food	7	2.4%
S4	56	18.9%
Other	12	4.0%
Method of provision of the complaint		
Letter	113	38.0%
Email	179	60.3%
Fax	5	1.7%
Type of complainant		
Anonymous	115	38.7%
Requested Anonymity	132	44.4%
Known	50	16.8%
Media in which the complaint appeared		
<i>Note: Some complaints appear in more than one medium</i>		
Print	70	23.6%
Broadcast	23	7.7%
Other Specified Media	5	1.7%
Internet	207	69.7%
Other	14	4.7%
Findings of the Panel		
Not Justified	0	0.0%

Justified	165	55.6%
Treated as Withdrawn	46	15.5%
Not within Jurisdiction	86	28.9%
Total	297	

Requests made by the Panel	Number	% of total found justified (165)
Withdrawal of Ad	162	98.2%
Withdrawal of Rep	147	89.1%
Retraction requested	46	27.9%
No Sanction	3	1.8%

Complaints Treated as Withdrawn	Number	% of total TAW (46)
Withdrawn 42ZCAF (a) Misconceived etc	24	52.2%
Withdrawn 42ZCAF (b) Previously dealt with by the Panel	11	23.9%
Withdrawn 42ZCAF(c) Another authority	14	30.4%
Withdrawn 42ZCAF (d)(i) Withdrawn by the Complainant	1	2.2%
Total Treated as Withdrawn	46*	

**Note: 4 complaints were TAW under 'Withdrawn 42ZCAF (b) Previously dealt with by the Panel' as well as 'Withdrawn 42ZCAF(c) Another authority' and have been recorded under both categories*

	Number	% of total TAW + Not within Jurisdiction (132)
Referred to NICNAS	4	3.0%
Referred to State Food Authority	6	4.5%
Referred to ASMI	1	0.8%
Referred to CHC	2	1.5%
Referred to TGA	80	60.6%
Referred to Other Body	2	1.5%
Recommendation to Secretary	44	
Referred to Regulatory Compliance Unit	79	

Timeframes

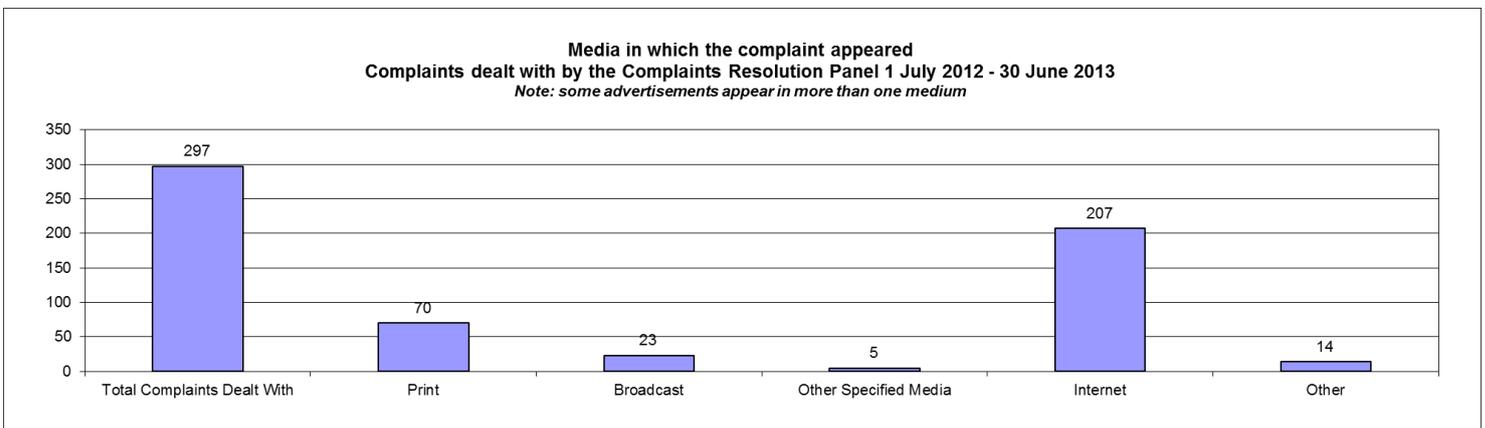
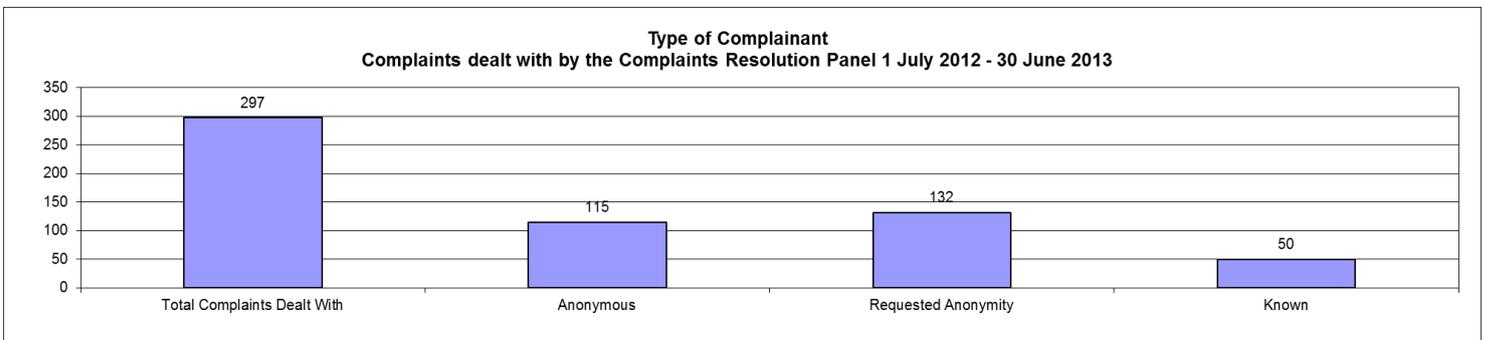
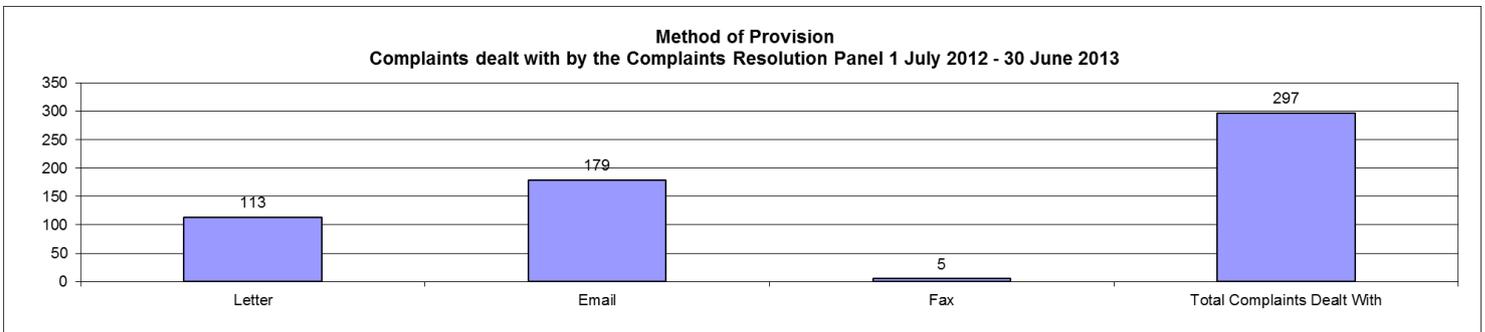
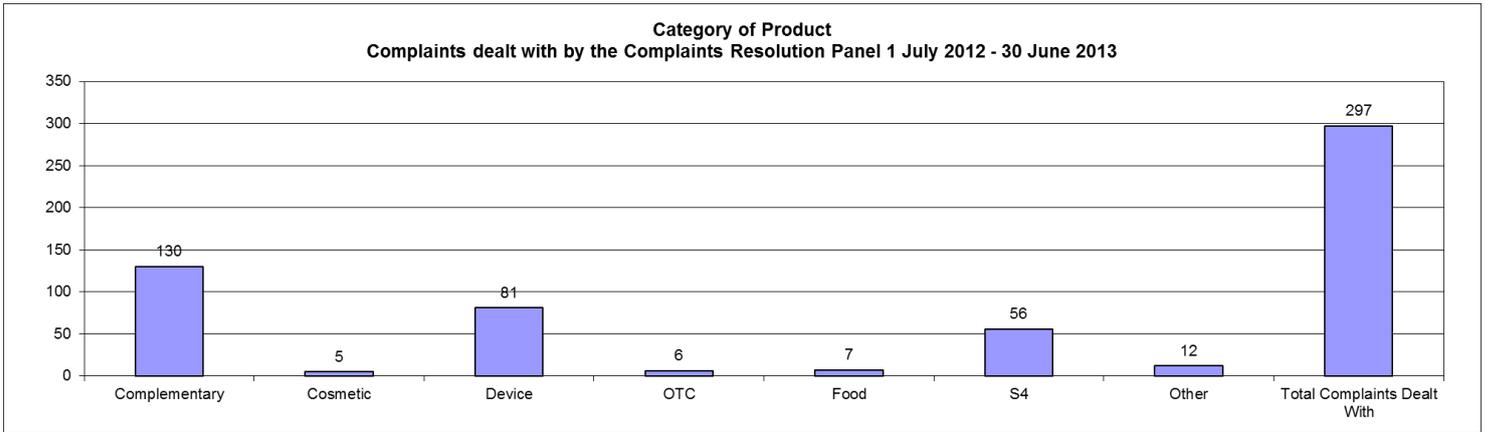
Averages (note: the averages cannot be summed)	Calendar days	2011/2012 financial year
Days from receipt to Panel	115	87
Days from Panel to determination sent	106	73
Days from receipt to determination sent	141	135

Summary of breaches

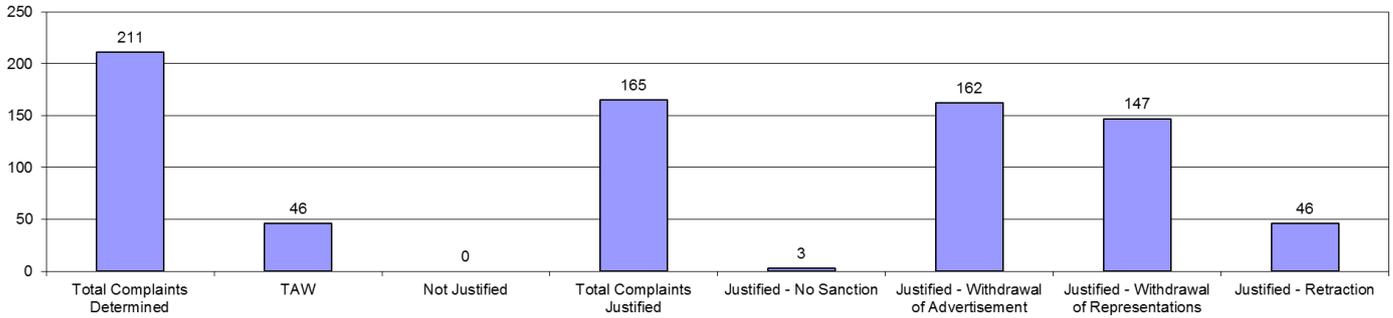
Act	Number Justified	% of total found justified (165)
22(5)	8	4.8%
41ML	2	1.2%
42C	31	18.8%
42DL(1)(a)	2	1.2%
42DL(1)(c)	8	4.8%
42DL(1)(e)	2	1.2%
42DL(1)(f)	2	1.2%
42DL(1)(g)	69	41.8%
42DM(1)	13	7.9%

Code	Number Justified	% of total found justified (165)
4(1)(a)	22	13.3%
4(1)(b)	121	73.3%
4(2)(a)	127	77.0%
4(2)(b)	34	20.6%
4(2)(c)	126	76.4%
4(2)(d)	57	34.5%
4(2)(e)	14	8.5%
4(2)(f)	14	8.5%
4(2)(g)	14	8.5%
4(2)(h)	13	7.9%
4(2)(i)	43	26.1%
4(4)	36	21.8%
4(5)	35	21.2%
4(6)	41	24.8%
4(7)	35	21.2%
4(8)	1	0.6%
5(1)	14	8.5%
5(2)	45	27.3%
6(3)	55	33.3%
6(4)	3	1.8%
7(1)	0	0.0%
7(2)	1	0.6%
7(3)	31	18.8%

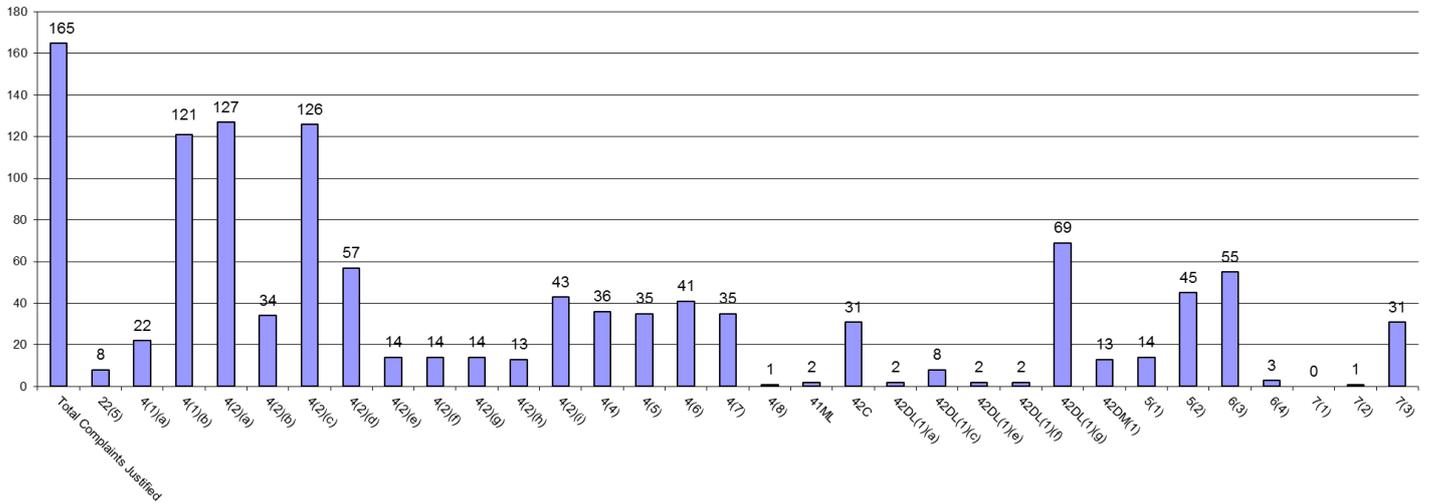
Graphical Representations of Complaints Summary 1 July 2012 – 30 June 2013



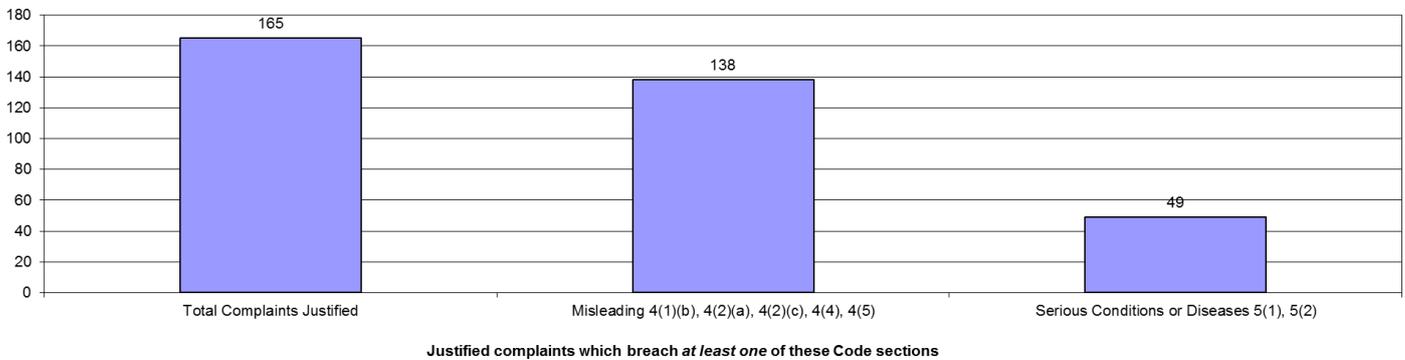
**Findings of the Panel and Sanctions
Complaints Determined 1 July 2012 - 30 June 2013**



**Summary of Breaches
Complaints Found Justified 1 July 2012 - 30 June 2013**



**Complaints which were found to be misleading OR refer to serious conditions/diseases
Complaints Found Justified 1 July 2012 - 30 June 2013**



Trends

