

**Report to the
Therapeutic Goods Administration on
the rates of compliance of advertisements
for therapeutic goods with the
Therapeutic Goods Advertising Code**

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In association with



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Executive summary

Introduction

The Interim Advertising Council (IAC) has been established by the TGA and Medsafe to develop a trans-Tasman regulatory model for the advertising of therapeutic products. A report on the proposed model is to be submitted to the TGA and Medsafe for the consideration of the Therapeutic Products Interim Ministerial Council. Amongst other things, this model needs to recommend an appropriate dividing line for approval of advertisements for therapeutic products.

Several models for the dividing line are being considered by the IAC. Before recommending a particular model, however, the IAC had agreed that research was required to answer such questions as the practicalities of the volume of material requiring approval, the additional costs of each of the possible approvals systems to industry and whether Australian material that is currently not subject to approval is more likely to breach the current Therapeutic Goods Advertising Code (TGAC) and the nature and severity of such breaches.

Currently, in Australia, all advertisements for designated therapeutic goods published for valuable consideration in specified media require approval before publication or broadcast. "Specified media" includes television, radio, newspapers, magazine, cinematographic film and outdoor advertising. This material is commonly known as "above the line" (ATL) advertising. All other forms of advertising do not require approval and are commonly known as "below the line" (BTL) material.

The aim of this project was to collect a worthwhile sample of performance data on ATL and BTL advertisements across a range of media to provide an indicator of the difference in compliance rates with the current Therapeutic Goods Advertising Code (TGAC) between advertisements for therapeutic goods that require approval prior to publication/broadcast and advertisements for therapeutic goods that do not require pre-approval.

Findings

A total of 306 advertisements across a broad spectrum of media categories were assessed for compliance with the TGAC. Ninety-three percent of advertisements subject to pre-approval (ATL) were compliant, with an infringement rate of 0.10 breaches per advertisement. The average compliance rate across three subcategories of BTL advertisements was 22%, with an infringement rate of 1.87 breaches per advertisement.

The majority of the breaches (62%) was in relation to the mandatory statements required under clauses 6.2 (a) & (d) of the TGAC. Various factors could be contributing to the high frequency of breaches in this area, most notably perhaps, a lack of clarity with regards to the exact requirements of these two clauses. A review of clause 6.2, particularly if it is proposed that these provisions be transferred into a new Australia New Zealand Therapeutic Products Advertising Code, might be justified.

When breaches of these clauses were disregarded, compliance and infringement rates changed significantly. Compliance with regards to ATL advertisements increased to 96% (0.04 breaches per advertisement) and the average compliance across all BTL advertisements more than doubled to 63%.

Guided by views previously expressed by IAC that public health and safety should be considered in terms of quality, safety and efficacy of therapeutic goods, 76 separate breaches of a more serious nature were identified in 52 of the 213 BTL advertisements (24%). The breaches included unapproved product indications and claims regarding diseases and conditions, which are either prohibited or restricted by the TGAC. When unapproved indications were disregarded, 20 of the 213 BTL (9%) advertisements reviewed included either prohibitions and/or restricted representations, which may have quite serious implications with regards to public health and safety.

Serious breaches constituted 19% of all breaches but when breaches of clause 6.2 (mandatory statements) were disregarded, the incidence of serious breaches increased to 51%. The infringement rate for all BTL advertisements with regards to serious breaches was 0.36 breaches per advertisement. Although only a relatively small sample of BTL advertisements was reviewed, it is of concern that advertisements for therapeutic goods which make serious, misleading therapeutic claims are being published under the current advertising scheme.

The findings of this survey indicate that compliance rates of advertisements which are subject to pre-approval are significantly higher than the rates for advertisements which do not require pre-approval. There were also no serious breaches in any of the advertisements which had been subject to pre-approval.

A review of education and monitoring programs implemented by industry bodies confirms industry's commitment to the promotion of the quality use of medicines through the active and ongoing promotion of responsible advertising practices.

Acronyms

ACCC	Australian Competition and Consumer Commission
APB	Australian Publishers Bureau
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self-Medication Industry
ATL	Above-the-line advertisements
BTL	Below-the-line advertisements
CAD	Commercials Acceptance Division (of CTVA)
CHC	Complementary Healthcare Council of Australia
CS	Collected Samples (from retailers & pharmacies)
CTVA	Commercial Television Australia
DS	Direct Sellers (sample category)
DSAA	Direct Sellers Association of Australia
IAC	Interim Advertising Council
IR	Infringement rate
OAAA	Outdoor Advertising Association of Australia
OTC	Over-the-counter
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGACC	Therapeutic Goods Advertising Code Council

Acknowledgements

A list of people who were consulted during the course of this project appears in Appendix 1 of this report. They have all been most helpful and generous with their time and we thank them for that.

Special thanks are due to the Project Officer and the Trans-Tasman team at the TGA and to the Executive Officer of TGACC, all of whom went out of their way to assist.

Finally we wish to express our sincere thanks and appreciation to those sponsors who assisted by submitting advertising materials. We recognise the additional effort asked of sponsors, but without these materials the study was not possible.

1 Introduction

Oceania Health Consulting formed a collaboration with Deon Schoombie to undertake research into the Australian system of regulatory controls in relation to the advertising of therapeutic goods. The aim of this research was to determine whether advertisements which are currently not subject to pre-approval are more likely to breach the current Therapeutic Goods Advertising Code (TGAC) and to assess the nature of such breaches.

The project commenced on 13 April 2004 and the date for the submission of a final report was set for 11 June 2004. Early discussions with key industry bodies and the TGA brought to light that the scope of the project and sponsors' ability to assist with the project required that the original timeline be revised.

It was agreed to extend the timeframe for the project to ensure collection of sufficient numbers of advertising materials to achieve adequate representation, to allow for realistic timeframes for sponsors to assist, and to allow time for the assessment of the volume of materials.

1.1 Aims of the project

There are several models for a new approvals system for advertisements of therapeutic goods in Australia before the Interim Advertising Council (IAC). The aim of the project is to provide an indicator of the difference in compliance rates with the current TGAC between:

- Advertisements for therapeutic goods which require approval prior to publication or broadcast, and
- Advertisements for therapeutic goods that do not require pre-approval.

This compliance indicator will, along with financial and time indicators from a separate project on costing, assist the IAC in determining the full resource impact of the implementation of these models.

1.2 Terms of reference

The terms of reference for the project are:

- To conduct a survey of a representative sample of advertisements for non-prescription medicines not subject to pre-approval ('below-the-line') including, but not limited to, the following categories:
 - direct mail, including direct and unsolicited mail;
 - catalogues;
 - point of sale material (e.g. brochures, pamphlets, posters, displays, shelf talkers);
 - websites, e-mails, SMS messages or any other electronic means;
 - press releases; and

- detail aids, promotions to retail staff, training materials.
- To conduct an equivalent survey of advertisements in the following media to enable a comparison to be made between ‘below-the-line’ and ‘above-the-line’ advertisements:
 - television, radio, cinema;
 - newspapers, consumer magazines, and
 - outdoor displays (eg. billboards, taxi signs, bus sides, shopping mall displays).

(In consultation with the TGA, it was decided to omit advertisements in trade / professional journals from this study as these advertisements are typically directed to healthcare practitioners and are therefore not required to comply with the TGAC under the current arrangements in Australia.)

- To record the following information in relation to the advertisements included in the sample:
 - Media type
 - Size / length of material
 - Location
 - Type of product (complementary medicine or OTC medicine (ie those medicines which are available without a prescription but are not complementary medicines).
- To assess advertisements for compliance with the Therapeutic Goods Advertising Code and to record the area/s of non-compliance.
- To provide an analysis of the data collected to demonstrate whether or not compliance with the Therapeutic Goods Advertising Code is notably different between those advertisements that have been approved prior to publication / broadcast, and those that have not.
- To consult the relevant industry associations (Medicines Australia, Australian Self-Medication Industry, Complementary Healthcare Council of Australia, Direct Sellers Association of Australia) about existing monitoring and education programs.

2 Methodology

2.1 Sampling strategy

Key stakeholders were consulted during the development of the sampling strategy. The consultants liaised with the relevant industry bodies to secure their assistance during the course of the project and to explore ways of maximising opportunities for gaining access to advertising materials.

All parties agreed that the volume of samples and the spread of these across a representative range of media categories were critical issues to address to ensure an appropriate sample size as well as a comparable sample of sponsors' advertising activities in the marketplace.

2.1.1 Determining sample categories

While the primary objective remained to determine whether there was difference in overall compliance rates between above-the-line (ATL) and below-the-line (BTL) advertisements, the sampling strategy was refined to test the possible impact of exposure to, and thus familiarity with the approval system on compliance rates of BTL advertising.

An assumption was made that while there is a spectrum of sponsors that regularly engage in ATL advertising ranging from big pharmaceutical companies on the one end to sole traders on the other, not all sponsors advertise in these media. Two examples are: those deterred by the cost of advertising in these media and as a result are more inclined to produce BTL advertising and promotional materials; and secondly direct sellers, a distinct category of sponsors whose advertising activities are almost entirely limited to BTL advertising.

With the above in mind, four main sample categories were identified and the targets in terms of number of advertisements to be included in each category, determined:

- ATL advertisements from all “specified media” categories – 100 advertisements
- ‘Matched’ BTL advertisements for the same products to facilitate direct comparisons with the ATL category – 100 advertisements
- Direct Sellers - 50 advertisements
- Advertisements of other sponsors mainly engaged in BTL advertising – 50 advertisements.

The target numbers were based on a balance struck between the requirement to achieve a reasonable number of samples and the volume of assessments which could be completed within the scope of the project.

The sample size of each of the “specified media” categories was selected according to the following targets, which were developed during a workshop/meeting with TGA personnel, and are based on assumptions about the approximate overall volumes of advertising activity as well as the likelihood of variability in term of compliance rates between the media categories:

- Print: 50%
- Radio: 30%
- Television: 10%
- Outdoor: 5%
- Cinema: 5%

2.1.2 Sourcing advertisements

Above-the-line/Below-the-line matched samples (ATL & BTL)

Samples in these two categories were to be obtained directly from sponsors by requesting them to submit all advertising materials produced within a specified period (first quarter 2004, last quarter 2003 or another recent quarter).

A list of 270 sponsors, which had advertised products in all therapeutic categories over a 12-month period across the entire spectrum of “specified media”, was compiled from media research reports. Fifty-four sponsors were then randomly selected – every fifth sponsor on a ranked list of sponsors according to total media-expenditure (“dollar-spend”) over a 12-month period.

A letter to sponsors was drafted with the collaboration of the main industry bodies (CHC, DSAA and ASMI) and mailed to the identified sponsors, who were asked to submit materials within three weeks. The mail-out was followed up by telephone calls to confirm receipt of the letter and the letter was faxed to sponsors who had not received the initial letter.

After the deadline for submission of materials was extended by another week, five companies (9%) responded and 35 advertisements were included in the survey sample.

These two sample categories are identified as “ATL” and “BTL”.

Direct sellers (DS)

Twenty-four direct sellers were identified with the assistance of the Direct Sellers Association of Australia (DSAA) and requested via the association to submit advertisements. Eight companies (33%) submitted a range of materials and 28 samples were included in the survey. This sample category is identified “DS” throughout the report.

Samples collected from pharmacies and other retailers (Collected Samples, CS)

Seventy items of promotional materials collected from pharmacies and health food retailers were entered into the survey sample. This category is referred to as “CS” throughout the report.

2.2 Revised sampling strategy

As a result of the limited response rates from sponsors, alternative methods had to be devised to make up for the shortfalls with regards to the set sample targets.

ATL advertisements were sourced in a variety of ways. The Therapeutic Goods Advertising Code Council (TGACC) had conducted two surveys in the last 2 years to determine the rates of compliance in relation to the requirement that print advertisements carry an approval number. All the advertisements from these surveys were made available for this project and 45 advertisements of sponsors who had been randomly selected from the media reports (see section 2.1.2 above) were included in the sample.

The remainder of the newspaper advertisements were sourced with the assistance of the Australian Publishers Bureau (APB). Additional magazine advertisements were sourced through a library search and copies of 5 additional TV commercials were purchased from the Television Register. All the advertisements included were from sponsors identified on the initial target list and were selected by finding matching TV commercials for BTL materials that were already in hand. It was not possible to supplement numbers with radio and outdoor advertisements as there are no centralised databases in the public domain from which these could be identified and sourced.

BTL samples were supplemented by collecting additional materials from pharmacies and health food retailers but mainly through the inclusion of 79 Internet advertisements collected from websites which could be identified as directed to an Australian audience.

A total of 306 advertisements were included in the final survey sample. Table 1 summarises the number of advertisements in each sample category and media type.

Table 1. Summary of materials included in each sample

Media	ATL	BTL	CS	DS	Total
TV	11				11
Radio	0				0
Magazines	32				32
Newspaper	50				50
Outdoor	0				0
Cinema	0				0
Web ads		57		22	79
Leaflets		18	44	6	68
Brochures		9	2		11
Catalogues			20	20	40
Posters		3	3		6
PR		2			2
Training materials				1	1
Giant packs			1		1
Shelf talkers		3			3
Email				1	1
Other (brand reminders)		1			1
Total	93	93	70	50	306

2.3 Validity of sample

2.3.1 Sample size and spread across media categories

As outlined earlier in this report, all stakeholders agreed that the number of advertisements and the spread across the range of media categories were critical issues. Notwithstanding the departure from the original sampling strategy, we regard the final sample as likely to be representative of the field, and a larger study over a longer time is unlikely to overturn the major findings of this report.

Targets were either exceeded or met in the CS and DS categories and we are satisfied that the sample sizes in the ATL and BTL categories are adequate. Ninety-three product advertisements from 42 sponsors were entered in the ATL/BTL categories, 70 advertisements from 21 sponsors in the CS category and 50 advertisements from 14 companies in the DS sample category.

In order to assess the validity of the spread across the range of media categories, we examined media research reports. These reports reflect total advertising expenditure across the range of “specified media” and an analysis of a 12-month period revealed the following ratios: TV advertising 57%, newspapers 16%, magazines 17%, radio 7%, outdoor 3% and cinema essentially nil.

While these figures do not translate directly into actual numbers of advertisements, in our view certain conclusions could be drawn from this data. TV advertising is considerably more expensive than other forms of advertising and an expenditure of 57% would translate into a considerably lower number of actual advertisements.

More importantly, the figures in relation to newspaper and magazine advertising showed that the vast majority of advertising activity (in terms of number of advertisements) occurred in print media - the number of advertisements included in the ATL sample could as a result be regarded as representative.

We do not believe that the absence of radio, outdoor and cinematographic advertisements detracts from the relevance of the sample, given the small percentages of total media expenditure in these media categories, although we recognise that radio advertisements would be numerous and variable, despite modest expenditure.

To our knowledge there is no benchmark data available in relation to BTL advertising to validate our survey sample. It could be argued that there was an over-representation of web advertisements, a result of the fact that we had to resort to sources of promotional materials which were readily available and easily accessible.

The issue of compliance of therapeutic goods advertising on the Internet has often been raised and we understand is currently subject to consideration by the TGACC. We believe that the inclusion of significant numbers of these advertisements in this survey could be regarded as an opportunity to gain some insight into compliance rates.

2.3.2 Distribution of complementary medicines and OTC medicines

Out of the total of 306 samples, 23% were advertisements for over-the-counter medicines (OTC) and 77% were for complementary medicines. For validation purposes we considered the number of non-prescription therapeutic goods currently on the Australian Register of Therapeutic Goods (ARTG). While it is not a reliable parameter in terms of exact numbers we believe it is nonetheless a useful benchmark indicator for the ratios of the two categories.

Of the current total of 18,731 non-prescription therapeutic goods, 20% are registered and 80% are listed therapeutic goods. While there are some registrable complementary medicines, we made the assumption (as agreed to by the TGA) that most complementary medicines on the ARTG would be listable goods and most OTCs registrable goods. Based on this assumption, we believe the ratio of 23/77 could be regarded as appropriate for the purposes of this project.

2.4 Data capture

The data in relation to each of the samples were captured under the four main sample categories identified in the sampling strategy – ATL (93), BTL (93), CS (70) and DS (50). Each advertisement was identified by its sample category (A, B, C or D), a 3-digit sample number and company identification (“c” plus 2-digit number). The type of product (OTC or complementary medicine); therapeutic category, media category, size and format of each advertisement were also recorded.

The sizes of the ATL advertisements were recorded using media terminology, e.g. FP (full page), ½-p (half page), etc. Where advertisements did not conform to these sizes, the sizes were recorded in number of words, e.g. 50-w (fifty word). This convention was also followed with regards to BTL advertisements. A full-page advertisement in the context of the Internet was an A4 printed copy of the relevant material.

Location by State and Territory was not recorded on the database. All ATL advertisements were published or broadcast nationally. It was impossible to determine the distribution of BTL materials, other than Internet advertising which is published nationally.

Each of the samples was assessed for compliance with the TGAC and breaches recorded under the relevant clauses of the TGAC. The total number of breaches per advertisement was recorded. Breaches of any clause of the TGAC were recorded as a single breach (“1”) for a particular advertisement, although more than one breach of a particular clause occurred in a number of instances.

Breaches of clause 4.1.1 of the TGAC occurred in 2 areas: unapproved indications (“UI”) which constitute a breach of Section 22(5) of the *Therapeutic Goods Act 1989* and the absence of an approval number in print advertisement (“NA”) which is a breach of Section 42(c) of the *Therapeutic Goods Act 1989*.

3 Findings

3.1 Overall compliance

Table 2 gives a summary of compliance and infringement rates (average number of infringements per advertisement) in each category. In the ATL category 93% of advertisements were compliant, 4% had a single breach, 1% had two breaches and 1% three breaches. The infringement rate for this category was 0.10.

In the matched BTL category 22% of advertisements were compliant, 9% had a single breach, 45% had two breaches. One advertisement had seven different breaches. In the CS category 35% of advertisements were compliant and the infringement rate was 1.47, while the figure in the DS sample was 6%.

While compliance was lower in the DS sample, compliance in the CS sample was higher than in the BTL sample and there was no evidence from this analysis to suggest that exposure to and familiarity with the pre-approval system contributed to improved compliance.

Table 2. Compliance and infringement rates

Number of breaches	ATL (%)	BTL (%)	CS (%)	DS (%)
0	87 (93)	20 (22)	24 (35)	3 (6)
1	4 (4)	8 (9)	17 (24)	12 (24)
2	1 (1)	42 (45)	10 (14)	21 (42)
3	1 (1)	14 (15)	11 (16)	3 (6)
4		4 (4)	6 (8)	5 (10)
5		3 (3)	2 (3)	3 (6)
6		1 (1)		2 (4)
7		1 (1)		1 (1)
Total breaches	9	178	104	117
Total adverts	93	93	70	50
Infringement rate	0.10	1.9	1.49	2.34

The data were analysed to determine whether breaches tended to be company specific. The infringement rate for each company was calculated and compared to the average infringement rate of 1.95 for all companies. There were several instances of high infringement rates per company but no clear pattern emerged. Company infringement rates are summarised in Table 3.

Table 3. Company infringement rates (IR)

Company	IR	Company	IR	Company	IR	Company	IR
ATL							
c01	0	c12	0	c24	0	c35	0
c02	0	c13	0.4	c25	0	c36	0.33
c03	0	c14	1	c26	0	c37	0
c04	1	c15	0	c27	0	c38	0
c05	0	c16	0	c28	1.5	c39	0
c06	0	c17	1	c29	0	c40	0
c07	0	c18	0	c30	0	c41	0
c08	0	c19	0	c31	0	c42	0
c09	0	c20	0	c32	0		
c10	0	c22	0	c33	0		
c11	0	c23	0	c34	0		
BTL							
c01	0	c12	2	c24	2	c35	1
c02	2	c13	3.8	c25	2	c36	2
c03	2	c14	1	c26	1	c37	2
c04	2	c15	2	c27	1	c38	2
c05	2	c16	2.5	c28	2	c39	2.5
c06	0	c17	3	c29	4	c40	1.75
c07	2	c18	0	c30	7	c41	3
c08	2	c19	0.33	c31	2.75	c42	2.5
c09	2	c20	0	c32	3		
c10	2.5	c22	3.5	c33	1		
c11	1	c23	1	c34	0		
CS							
c01	3	c07	3.43	c13	0.5	c19	2
c02	1.83	c08	1.67	c14	4	c20	1
c03	0.54	c09	0	c15	3	c21	3
c04	1	c10	1.33	c16	0		
c05	0	c11	1	c17	0.5		
c06	1	c12	3	c18	4		
DS							
c01	1	c05	2	c09	2	c13	3
c02	1.25	c06	1.2	c10	1.5	c14	1.5
c03	3.67	c07	2.6	c11	5.4		
c04	2	c08	6	c12	2		

Infringement rate (IR) = number of breaches per advertisement

3.2 Areas in which breaches occurred

Table 4 highlights the areas where breaches occurred and the number of breaches of the various clauses of the TGAC. The clauses were paraphrased for the sake of brevity and to provide a ‘snapshot’ view of the data.

Table 4. Numbers of breaches for each clause of the Therapeutic Goods Advertising Code

Clause	Description	ATL	BTL	CS	DS
4.1.1 – UI	Unapproved indication		15	16	9
4.1.1 – NA	No approval number in print ad	1			
4.1.2(a)	Unwarranted, unrealistic product expectations		4	9	
4.1.2(b)	Self-diagnosing, inappropriately treating serious diseases		1	2	
4.1.2(c)	Misleading directly or by implication		1	1	3
4.1.2(g)	Product infallibility			3	
4.1.2(i)	Product safe, can cause no harm, no side-effects		4	3	2
4.2	Scientific information	1	5	9	3
4.3	Comparative advertising			1	1
4.4.1(a)	Endorsement by govt. agency		4		5
4.4.1(b)	Endorsement by hospital, healthcare facility			1	
4.4.1(c)	Endorsement by healthcare professional	1	5	6	3
4.4.2(b)	Endorsement by research facility	1	1		
4.5	Testimonials		2		1
5.1	Prohibitions – cancer, STD, HIV/AIDS, HCV, mental illness		4	2	6
5.2	Restricted representations – serious diseases		6	2	4
6.2(c)	Mandatory: “Always read label” or list of ingredients	3	62	10	45
6.2(d)	Mandatories: “Use only as directed”, “If symptoms persist, see HCP”	2	64	35	33
7.2	Vitamins not substituting for good nutrition				1
7.3	Weight management – inclusions of lifestyle factors			4	1

3.2.1 Breaches in the ATL sample

A total of 9 breaches were found in this sample, all in print advertisements.

One breach was in relation to the absence of an approval number. This could be due to the fact that the advertisement had not gained pre-approval, or it had in fact gained pre-approval but the approval number had not been inserted prior to publication.

There was one breach of clause 4.2, which requires that claims in relation to the results of scientific studies be referenced. There were two breaches of clause 4.4 - one advertisement claimed endorsement by a healthcare professional and the other endorsement by a body conducting research and delivering healthcare services. In three of the advertisements there were five instances of breaches of clauses 6.2 (c) and (d) – all in relation to the mandatory statements required by these clauses.

3.2.2 Breaches of clause 6.2 of the TGAC

The majority of breaches of the Code occurred in relation to the mandatory statements required under clauses 6.2(c) – 120 breaches and 6.2(d) – 134 breaches. These breaches accounted for 62% of all breaches when the 4 samples were considered collectively.

We believe that this finding warranted further exploration as it skewed the picture of overall compliance. The data were also analysed after exclusion of breaches of these two clauses. Table 5 provides a summary of the amended compliance and infringement rates.

Table 5. Compliance & infringement rates excluding breaches of clauses 6.2 (c) & (d)

Number of breaches	ATL (%)	BTL (%)	CS (%)	DS (%)
0	89 (96)	61 (66)	40 (58)	34 (68)
1	4 (4)	20 (22)	12 (17)	5 (10)
2		6(6)	8 (11)	4 (8)
3		4 (4)	9 (13)	3 (6)
4		1 (1)	1 (1)	3 (6)
5		1 (1)		1 (2)
Total	4	53	59	39
Ads	93	93	70	50
Infringement rate	0.04	0.57	0.84	0.78

While compliance remained significantly better in the ATL sample, compliance rates in the 3 other categories not only improved significantly, but more ‘comparable’ compliance and infringement rates emerged between the 3 categories. Compliance rates increased to 66% in the BTL sample, to 58% in the CS sample and to 68% in the DS sample – resulting in an overall average of 63%.

This analysis did not provide conclusive evidence that exposure to the pre-approval process resulted in noticeably better compliance with regards to BTL advertising.

Historically there had been a tendency to ‘hide’ the mandatory statements at the bottom of advertisements where they were cited with the company address details and other information not directly linked to the therapeutic and advertising claims made in the main body of the advertisement. During the development of the current TGAC at the time of the review of advertising controls in 1999/2000, these clauses were revised to make it clear that the mandatory statements needed to be “*prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood*”.

The requirements were intentionally framed in such a way as to allow for a degree of interpretation in accordance with the spirit of a ‘principle-based’ Code. While we acknowledge the principle-based nature of the TGAC, the degree of ‘openness to interpretation’ in relation to these clauses might be a contributing factor to the high frequency of breaches.

Another area of possible confusion could be the exception in clause 6.2 (c) in relation to direct marketing and Internet marketing. It is a requirement that advertisements in these categories display a full list of active ingredients (to enable consumers to make an informed decision about the product before purchase) AND the mandatory statement: “*Always read the label*”.

For the purposes of this study, we accepted the mere inclusion of the required mandatory statements as constituting compliance, regardless of the fact that the statements were often not necessarily “prominently displayed”. However, we noted a wide variety of approaches to implementation of these clauses, ranging from the inclusion in the main body of the advertisement in the same font as the body copy, to statements “hidden away” in the smallest font and separated from the main body of the advertisement.

3.3 Nature of breaches

The IAC had previously agreed that public health and safety should be considered in terms of the quality, safety and efficacy of therapeutic goods (refer minutes of IAC meeting 20/21 November 2003). In an advertising context, this could translate into risk caused by advertisements that made the following range of claims: claims beyond the approved indications; those promoting self-diagnosis and treatment of serious forms of diseases; claims that the products are safe, can cause no harm or have no side-effects; claims promoting excessive use or the failure to disclose adverse reactions of clinical importance.

Breaches were analysed using the position held by the IAC as a guideline.

3.3.1 Unapproved indications

Table 6 summarises breaches of clause 4.1.1 in relation to unapproved indications - Section 22(5) of *Therapeutic Goods Act 1989*.

Table 6. Unapproved indications found during the study

Product	Company	Claims
ATL		
Nil	Nil	Nil
BTL		
B006	c05	Relieve dry skin, eczema & PMS symptoms
B023	c09	Relief of fevers
B029	c10	Helps maintain a healthy nervous system
B035	c13	Its antioxidants protect the eyes, cardiovascular & central nervous system
B036	c13	Proven to lower blood pressure, used in treatment of insomnia, neuralgia, shingles, hyperactivity in children (including ADD), seizures of Parkinson's disease, epilepsy, asthma, whooping cough rehabilitation of drug & alcohol dependency, depression, dysentery, hysteria, ear & headaches, dysfunctional labour, prevention of heart disease
B037	c13	Dramatically improves impotence, diminishes fatigue & lethargy and improves mental alertness, reduces nervous exhaustion, debility & poor vitality
B042	c16	Useful for athletes with overtraining syndrome associated with poor resistance to infection as a pre-competition immune system booster
B056	c22	Assists wound healing, prevention of muscular cramps
B057	c22	Reduces symptoms of mild to moderate depression & other mood problems
B067	c29	Viagra alternative, indicated for low libido, loss of sexual performance
B068	c30	Alternative to blood transfusion for anaemia
B071	c31	Used for sexual dysfunction, depression and infertility
B072	c31	Enhances stamina
B079	c36	Provide significant reductions in defects of the heart, urinary tract, limbs and gastro-intestinal tract. Also protects against cleft palate, reducing the risk of premature birth & low birth weight
B091	c42	For prevention of hayfever

Table 6. Unapproved indications found during the study (continued)

Collected samples		
C004	c02	Improves peripheral circulation & prevents cold hands & feet
C006	c02	For abnormal cholesterol
C013	c03	Supports the brain against age-related memory decline, enhances mood & prevents mood decline
C020	c03	For high cholesterol
C027	c07	Lowers cholesterol
C029	c07	Of value in the treatment of Alzheimer's disease
C030	c07	For relief of depression
C031	c07	For relief of symptoms of depression
C039	c10	Helps ease digestion
C060	c18	For depressive moods & mood swings
C062	c20	Mood elevator
C063	c20	For gastritis, eczema, poor circulation & worms, weight loss
C065	c21	For tendency to constipation
C067	c21	Useful for difficulty with sleeping
C068	c21	For poor liver function
C070	c21	For gastritis, Candida & thrush
Direct sellers		
D001	c01	Indicated for mild to moderate depression
D010	c03	Supports normal blood glucose & helps reduce inflammation
D024	c07	Supports nose & lung tissue, promotes respiratory health
D025	c07	For weight management, controls appetite
D027	c08	Increases energy & stamina, promotes faster recovery, increases memory & mental capacity, improves concentration & mood, reduces headache & migraine, helps coping with stress
D039	c11	Boosts the cardiovascular system
D040	c11	An expectorant for coughs & colds
D042	c11	Assists with symptoms of depression
D043	c11	Treats depression & prevents age-related memory loss

The list contains a wide range of indications. Some could be regarded as relatively innocuous and posing a low risk to the health and safety of consumers, while others made claims in relation to more serious conditions with significant public health and safety implications. We did not attempt to determine whether any particular indication(s) was appropriate for that particular product, we only recorded indications which had appeared in advertisements and where those indications were not recorded on the ARTG.

However, it needs to be noted that while several of the indications arguably may have been appropriate for the particular product (had appropriate evidence been held and the indications/claims included in the ARTG), there were also instances where the indications would definitely not have been appropriate for the particular product (based on the ingredients or because of the restrictions under clause 5 of the TGAC). These are highlighted in the next section.

3.3.2 Clause 5 of the TGAC – Prohibitions and restricted representations

Tables 7 and 8 list representations that appeared in advertisements which are either prohibited by the TGAC (clause 5.1), i.e. neoplastic diseases (including cancer), sexually transmitted diseases (STD), HIV/AIDS and/or HCV and mental illness; or are restricted (clause 5.2) because of the serious nature of such diseases or conditions.

Table 7. Prohibitions

Product	Company	Prohibition
B036	c13	Mental illness – ADD, including hyperactivity in children, drug & alcohol dependency, depression
B057	c22	Mental illness - depression
B065	c29	Mental illness - depression & anxiety disorders
B071	c31	Mental illness - depression
C030	c07	Mental illness - depression
C031	c07	Mental illness - depression
D001	c01	Mental illness - depression
D027	c08	Mental illness - depression, post-traumatic stress disorder, anorexia nervosa
D041	c11	Neoplastic disease- breast cancer
D042	c11	Mental illness - depression
D043	c11	Mental illness - depression
D048	c13	Neoplastic disease - breast & prostate cancer

Table 8. Restricted representations

Product	Company	Restricted representation
B036	c13	Heart disease, dysfunctional labour, dysentery, whooping cough, shingles
B037	c13	Male impotence
B068	c30	Anaemia, Crohn’s disease
B071	c31	Infertility, sexual dysfunction
B079	c36	Birth defects of heart, urinary tract, limbs; premature birth
B083	c39	Haemochromatosis, haemosiderosis
C029	c07	Alzheimer’s disease
D012	c03	Diabetes, asthma, strokes
D027	c08	Asthma, epilepsy, seizures
D040	c11	Cardiovascular disease
D048	c13	Heart disease

3.3.3 Summary of serious breaches

A total of 76 breaches of a more serious nature were identified, all of which occurred in the three below-the-line sample categories. This figure represents 19% of the total of 399 breaches in these three samples. For the same reasons mentioned earlier, the data were also analysed after excluding breaches of clauses 6.2 (c) and (d). Breaches of a more serious nature then constituted 51% (76 of the 150 remaining breaches).

Twenty (9%) of the 213 below-the line advertisements contained references to either prohibitions and/or restricted representations.

3.4 Comparisons between Internet advertising and other BTL advertisements

3.4.1 Overall compliance

There is a view held by some that web advertisements are generally less compliant than other below-the-line advertisements. Given the large number (79 or 37%) of web advertisements in the survey sample, we considered it appropriate to investigate comparative compliance rates. The tables below summarise the findings when all breaches were taken into consideration.

The infringement rate for web advertisements was 2.45, compared to an infringement rate of 1.53 for all other below-the-line advertisements. However, the picture that emerged after exclusion of breaches of clauses 6.2 (c) and (d) (being in relation to mandatory statements), was again very different. There appeared to be no meaningful difference in compliance rates. The net infringement rate was 0.65 for web advertisements and 0.68 for all other below-the-line advertisements.

Table 9. Compliance rates of Internet vs other BTL advertisements

	Websites		Other materials		
	BTL	DS	BTL	DS	CS
Advertisements	57	22	36	28	70
Breaches	123	71	55	46	104
Total ads	79		134		
Total breaches	194		205		
Infringement rate	2.45		1.53		

Table 10. Compliance rates of Internet advertising vs other BTL advertisements- excluding breaches of clauses 6.2 (c) & (d)

	Websites		Other materials		
	BTL	DS	BTL	DS	CS
Advertisements	57	22	36	28	70
Breaches	29	22	23	11	58
Total ads	79		134		
Total breaches	51		92		
Infringement rate	0.65		0.68		

3.4.2 Serious breaches

The data were also analysed to determine whether there was a difference between Internet advertisements and other below-the-line advertisements in relation to the incidence of serious breaches. Applying the same criteria as above for defining more serious breaches, the infringement rate for the 79 web advertisements was 0.42 (33/79) and the rate for the other below-the-line advertisements was 0.32 (43/134).

Ten (13%) of the 79 web advertisements contained breaches in relation to prohibited and/or restricted representations while 10 (7%) of the 134 remaining below-the-line advertisements contained similar breaches.

3.5 Summary of findings on infringement rates

A total of 306 advertisements from 77 companies were included in this survey. The advertisements covered a broad range of specified and below-the-line media categories. Twenty-three percent of advertisements were for OTCs and 77% were for complementary medicines.

We are confident that the survey sample was relevant both in terms of number of advertisements as well as spread across the range of media categories and type of product.

The compliance rate for advertisements which had been subject to pre-approval (94%) was substantially higher than the rate for advertisements which did not require pre-approval (22%). The highest frequency of breaches occurred in relation to the mandatory statements required under clauses 6.2 (c) and (d) of the TGAC. We believe this phenomenon could be partly explained by the lack of clarity of the particular clauses and that in developing a new Australia New Zealand Therapeutic Products Advertising Code, a review of the existing wording of these clauses might be justified.

When breaches of these two clauses were excluded, the compliance rate for advertisements which had been subject to pre-approval increased to 96% and the compliance rate for below-the-line advertisements was 63%.

Guided by the view expressed by the IAC in relation to public health and safety, serious breaches were regarded as: claims containing unapproved product indications, prohibitions and restricted representations as defined under clause 5 of the TGAC; and claims in relation to the safety and side-effect profile of the product.

When all breaches were taken into consideration, serious breaches constituted 19% of breaches but when breaches of clauses 6.2 (c) and (d) were excluded, serious breaches accounted for 51% of breaches. This translated into an infringement rate of 0.36 serious breaches per advertisement.

Infringement rates between Internet advertisements and other below-the-line advertisements were compared – when all breaches were taken into consideration, the rate for web advertisements was 2.45 compared to 1.53 for other below-the-line advertisements. When breaches of clauses 6.2 (c) and (d) were excluded there was essentially no difference between the infringement rate for web advertisements (0.65) and other below-the-line advertisements (0.68).

The infringement rates for web advertisements and other below-the-line advertisements with regards to breaches of a more serious nature was 0.42 and 0.32 respectively.

Breaches in relation to prohibited and/or restricted representations may have quite serious public health and safety implications. Nine percent of all below-the-line advertisements contained references to these representations - 13% occurred in web advertisements and 8% in other below-the-line advertisements.

3.6 Conclusion

Analysis of the data collected demonstrated that compliance with the Therapeutic Goods Advertising Code is notably higher for those advertisements that had been approved prior to publication or broadcast than for those that had not.

4 Education and monitoring programs

4.1 Introduction

Upon commencement of the *Therapeutic Goods Act 1989*, the Commonwealth government accepted a continuation of the system of self-regulation of advertising and promotion by the non-prescription medicines industry. A two-year trial period was proposed after which the regulatory bodies would review the operation of the system to determine whether the voluntary industry codes and legislatively regulated codes had been handled accurately and responsibly by industry.

Since then the various codes of practice developed by the key industry bodies have become firmly established and important elements of the process of self-regulation, within the overall co-regulatory system for advertising and promotional activities of the industry.

Under these codes a wide range of educational and monitoring programs have been implemented. This section of the report provides a brief overview of those activities.

4.2 The Australian Self-Medication Industry (ASMI)

4.2.1 The ASMI Code of Practice

The Australian Self-Medication Industry Association (ASMI) represents the interests and activities of companies involved in the manufacturing and marketing of non-prescription consumer medicines. The current membership of ASMI is estimated to represent the marketers of more than 75% of the consumer medicines market, as well as companies providing services to manufacturers, such as contract packaging, advertising, regulatory consultancy and industry statistics.

The ASMI Code of Practice came into force in 1977 and acceptance and observance of the Code is a binding condition of membership of ASMI. A comprehensive review of the Code is undertaken annually to respond to the dynamic environment of government legislation, consumer concerns and the business market place.

Under the authorisation of the Code granted by the ACCC in 1996, ASMI is required to widely publicise the existence of the Code and the complaints procedures to consumers and the healthcare professions. It also requires that complaints are accurately processed, monitored and reported.

4.2.2 Advertising and Promotional Activities

The ASMI Code of Practice incorporates the advertising requirements of the Therapeutic Goods Advertising Code (TGAC) but extends to also cover members' promotional activities directed to healthcare professionals. The definition of an

advertisement is adopted from the *Therapeutic Goods Act 1989*, but is extended to include promotional activities not covered by the TGAC. Promotional materials which are not subject to formal pre-approval, must still comply with the TGAC, and ASMI's Advertising Services Office offers advice to members in relation to compliance of these materials with the TGAC and the ASMI Code of Practice.

Like the TGAC, the ASMI Code requires that all information and therapeutic claims about products be current, accurate and balanced. Claims must not mislead, must be capable of substantiation and comparisons between products must be based on fact and reflect the body of scientific evidence. However, certain provisions of the Code of Practice are more restrictive than the TGAC, for example, advertising of S3 products (i.e. those in Schedule 3 of the *Australian Standard for the Uniform Scheduling of Drugs and Poisons*) to healthcare professionals must conform to defined standards and include specific categories of information and promotional activities should not attempt to persuade consumers to purchase unnecessary non-prescription medicines or in excessive quantities.

4.2.3 Complaint and appeal processes

A complaints handling function is undertaken by ASMI in accordance with the Code of Practice. Any member of the public, healthcare professions or industry may lodge complaints regarding breaches of the Code.

For industry-generated complaints, the two parties are encouraged to resolve the issue informally prior to the complaint being submitted to the Complaints Panel.

The Complaints Panel is chaired by a lawyer with trade practices experience, and comprises a nominee from the Royal Australian College of General Practitioners, a community pharmacist, three members from ASMI member companies and a consumer representative. A representative of the Department of Health and Ageing is present as an observer.

The Complaints Panel can apply a range of sanctions if it determines that the Code had been breached. Sanctions include a member being required to undertake in writing to discontinue the practice, or to issue retractions or corrective statements. In addition, a fine may be imposed, the size of which depends on the severity of the breach. The breaches and the sanctions are publicised in the ASMI Annual Report. The Complaints Panel can recommend that the Committee of Management apply further sanctions, including suspension of membership or expulsion from ASMI.

The Code makes provision for an appeals process and complainants and disciplined members can appeal against decisions of the Complaints Panel. An independent arbiter considers all appeals.

Over the last three years, an average of eight complaints per year have been determined and 60% have been upheld. During this period an average of three appeals per year have been received and of those 75% were dismissed.

4.2.4 Proactive monitoring

While complaints handling could be regarded as a 'reactive' mechanism to ensure compliance, the ASMI Code also makes provision for a proactive mechanism to support and encourage compliance with the TGAC and ASMI Code. The Promotional Monitoring Panel monitors promotional materials and activities of members on a regular and ongoing basis according to a schedule determined by the Marketing & Ethics Subcommittee. This ensures coverage of all therapeutic categories and all types of promotional materials in regular cycles and within a specified period.

The aims of the monitoring process are to encourage compliance with the Code through the review of all non-mainstream advertising materials; to provide comment on compliance issues where requested and to provide an ongoing mechanism for the identification of changing trends, which may indicate the potential need for amendments to the Code. It generates and publishes statistical data on the rates of compliance which demonstrates in a transparent way industry's commitment to promoting compliance with all advertising controls.

Over the last three years the Promotional Monitoring Panel has reviewed an average of 450 items per year. Of these, approximately 19% were found to be non-compliant with the TGAC and ASMI Code of Practice. The vast majority of non-compliance was due to lack of appropriate mandatory statements.

4.3 Complementary Healthcare Council of Australia (CHC)

4.3.1 The CHC Code of Practice

The CHC established a self-regulatory process for the complementary healthcare industry in the early 1990s. Its focal point is the Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products, which seeks to self-regulate the marketplace by encouraging compliance with relevant Commonwealth and States & Territories legislation.

The Code of Practice was developed in close consultation with the ACCC and has been reviewed by the ACCC on three occasions since 1995. The Code does not contain any anti-competitive requirements and as a result does not require authorisation.

Adherence to the Code is a mandatory requirement of CHC membership and non-members are invited and encouraged to accept and abide by the Code.

4.3.2 Complaints Resolution Committee

The Complaints Resolution Committee (CRC), established under the provisions of the CHC's Code of Practice, comprises industry representatives, direct marketing/selling professionals, consumer groups and Government authorities. In the main, the CRC considers complaints about non-mainstream (non-specified) media advertisements for complementary medicines but complaints about foods are also considered. All complaints, whether concerning members or non-members of the CHC, are acknowledged by the CRC.

The Committee considers complaints against the *Therapeutic Goods Act 1989 & Regulations*, the Therapeutic Advertising Code and the CHC Code of Practice. Where the Committee considers breaches have occurred, it may apply a range of sanctions, which are applied to non-members as well as members.

The CRC may request withdrawal and destruction of the offending material, that future distribution is ceased, that websites be amended, and in some cases that public retraction statements are published. In cases of repeat offenders, the Committee may request that all future non-mainstream advertisements be approved prior to publication, even though this is not required by law.

In the rare cases where the required action is not taken, the CRC refers the matter to the TGA, ACCC, State Regulator or FSANZ, as appropriate.

Should the Committee consider material to be in breach of requirements and impose sanctions, the Code of Practice provides for an appeal process whereby an organisation which is the subject of a complaint may request the CRC to review its decision.

Over the last five years, the CRC has handled more than 1661 complaints (836 formal and 825 informal), with a 95% success rate for complementary medicines

The complaints procedure also has an important educative role that results in improved advertising of complementary medicines and compliance with the CHC Code of Practice and Australian regulatory requirements. CRC determinations assist sponsors and advertisers to understand the variety of possible interpretations of their promotional material and particularly how consumers may perceive them. Most sponsors and advertisers are accepting of the CRC's interpretation and cooperate with the determinations to ensure that advertising meets the standards and professionalism expected by the industry and consumers.

The effectiveness of, and support for, the CRC is also demonstrated by the significant number of sponsors/advertisers who respond to the initial CRC advice of the complaint by undertaking action to remedy the issues raised prior to the CRC officially assessing the complaint.

The CRC has found that sponsors/advertisers using the services of the Advertising Services Office, which is responsible for the mandatory clearance of advertisements intended for publication in specified media, avoid misunderstanding and potential breaches of advertising requirements. Although it is not mandatory to have non-mainstream materials cleared, the CHC encourages sponsors/advertisers to utilise the service during the development of their promotional materials.

4.3.3 Ongoing education

The CHC has implemented a program of ongoing education. Workshops are offered on a regular basis and these are offered on-line, in-house or within group settings. These workshops have been well-received and attended with up to 220 registered delegates. Printed educational materials are also distributed to sponsors who come into contact with the complaints process.

4.4 Direct Sellers Association of Australia

4.4.1 The DSAA Code of Practice

A National Association of Direct Selling Organisations was formed in 1967 to promote and protect the ideals and opportunities for this particular industry. One of the Statements of Purpose of the Association is to foster and promote ethical methods of direct selling within the community.

The Constitution required that a Code of Practice be established and adopted by members as the fundamental trading standard to provide protection for consumers. Acceptance of the Code is a requirement for membership and all members must agree in writing to be bound by the Code. It is a condition of membership that members are familiar with the content of the Code and that it is strictly observed.

The basic principles of the Code require, amongst other, that all sales activities be conducted in accordance with the laws of the Commonwealth, States and Territories and that members must ensure that all direct salespersons are properly informed in order to provide consumers with all relevant information in relation to products and transactions.

Members are required to establish and maintain satisfactory systems to ensure the relevant employees and direct salespersons are properly and adequately informed of the existence and requirements of the Code.

The Code specifically addresses product safety and advertising practices. Members must ensure that all therapeutic goods (including therapeutic devices) offered for sale, comply with Commonwealth and State health and licensing requirements and labelling laws. Advertisements and promotional materials in relation to products and their recommended use must not contain any description, claim or illustration which directly or by implication is deceptive or misleading. All claims and testimonials published or advertised must be capable of substantiation.

4.4.2 Consumer complaints handling

DSAA guarantees consumers access to a simple, quick, effective and cost-free method of redress of complaints against a Member and its salespersons with regard to breaches of the Code.

Each Member must have in place a system for dealing with complaints from consumers. The system must meet the minimum requirements of the Association as advised to members from time to time. Details of the complaints handling system must be made available to consumers upon request and members are also required to maintain records of all consumer complaints – date of complaint, the consumer’s details, the decision and details of how it was communicated to the consumer.

In the event that a consumer is not satisfied with the action or decision of a Member, the Member must refer the complaint to the Executive Director of the Association. The Executive Director will seek to resolve the complaint with the Member and the Consumer within 10 days and, failing that, will refer it to the Code Administrator for resolution under this Code.

The Code Administrator is an independent person appointed by the Board under the requirements of the Code of Practice. The Administrator determines after investigation whether further action is required.

4.4.3 Consumer Complaints Resolution Panel

The Panel is comprised of the Code Administrator (chairman), a person nominated by the Director of Consumer Affairs in the State in which the hearing is to take place (to represent the Director); a person nominated by the chairman of the Consumers Federation of Australia to represent consumers, and a person nominated by the Executive Director of DSAA, to represent industry.

The Panel convenes only to determine complaints which involve a complaint from a consumer against a Member. A consumer, a Member, the Board or the Code Administrator may request a hearing by the Panel.

The Panel is empowered to impose a range of sanctions. This may include a requirement that a Member found in breach of the Code, implements a compliance program approved by the Code Administrator.

A summary of complaints referred to the Code Administrator is published in the Annual Report of the association.

4.4.4 Monitoring

Members' complaints handling and other systems and procedures are monitored by DSAA to the extent required to ensure that they are adequate to permit members to discharge their obligations under the Code. A summary of monitoring activities on members' complaints handling systems is published in the Annual Report.

Other DSAA activities which are designed to monitor and improve compliance with advertising controls include the following:

- **Therapeutic Goods Committee**

This committee was established in 2003 and consists of representatives of six members. The purpose of the Committee is to keep members informed of the laws and regulations in relation to therapeutic goods and, in particular, the requirements of the Therapeutic Goods Advertising Code. The Committee meets not less than quarterly or as required.

- **Therapeutic Goods Special Interest Group (TGSIS)**

The Group meets twice per year and provides an opportunity for all members involved in the sale and distribution of therapeutic products, to come together for detailed briefings and discussions on legislation, regulations, and current developments in the therapeutic goods area. The TGSIS is generally convened at the AGM (July), Annual Conference (October), and at other times as required.

- **Newsletter**

The Association publishes a regular newsletter which contains a "Regulatory Update" section. This provides an additional vehicle to keep members informed of current developments in the regulatory arena.

4.5 Medicines Australia

4.5.1 Medicines Australia Code of Conduct

In November 2003, Edition 14 of the Medicines Australia Code of Conduct received authorisation from the ACCC. Compliance with the provisions of the Code of Conduct is mandatory for members of the Medicines Australia. Compliance with the Code in relation to the marketing and promotion of prescription medicines is also required for companies who are not members of the Association through the marketing approval letter issued by the TGA.

If a complaint is lodged against a non-member company and that company refuses to have the matter considered by the Code of Conduct Committee, Medicines Australia reserves the right to refer such matters to the Therapeutic Goods Administration (TGA) or the Australian Competition and Consumer Commission (ACCC).

4.5.2 Code of Conduct Program

The Code of Conduct has two arms, firstly the adjudication of complaints undertaken by the Code of Conduct Committee and secondly the proactive monitoring of promotional activities undertaken by the Monitoring Committee.

- Code of Conduct Committee

Complaints regarding promotional activities are accepted from any individual or organisation. Assistance can be provided to those individuals who are unsure of how to complain or what a complaint should contain. Once a complaint is received it is sent to the company whose promotional activities are being questioned and this company provides a response to the issues raised in the complaint.

The complaint and response are considered by the independent Code of Conduct Committee. The Committee is comprised of the following members:

Full members:

Chairman, a lawyer with Trade Practices experience; a representative of the Australian Medical Association (AMA); a representative of the Royal Australian College of General Practitioners (RACGP); a representative of the Australian Divisions of General Practice (ADGP); a representative of a patient support group, preferably with specialist qualifications; a representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT); a representative of a consumers' organisation; three Medicines Australia Association Representatives and two Medicines Australia Medical or Scientific Directors.

Advisors:

The Code of Conduct Secretary; the Medicines Australia CEO or delegate and the Medicines Australia officer responsible for Scientific and Technical Affairs

Observers:

A representative of the Therapeutic Goods Administration (TGA); a member of the Medicines Australia Marketing Committee; two employees of Medicines Australia member companies and an observer interested in the Code process.

The Committee determines whether a breach of the Code of Conduct has occurred and if so, the appropriate sanction that should be imposed.

The Code of Conduct contains a variety of sanctions if a promotional activity is found to be in breach. These sanctions include the immediate withdrawal or cessation of the promotional activity, the publication of corrective advertising, the requirement to send a corrective letter, the imposition of fines up to \$200,000 and suspension or expulsion from the Medicines Australia membership.

In 2002/2003 Medicines Australia received 48 complaints from member and non-member companies, the Therapeutic Goods Administration, healthcare professionals, consumer organisations and academics. During this period the Committee imposed corrective advertisements on three companies, corrective letters on two companies and a total of \$310,000 in fines.

An independent Appeals Committee also exists to consider appeals by companies if their promotional materials or activities have been found in breach of the Code.

- The Monitoring Committee

To complement the activities of the Code of Conduct and promote compliance with the Code, a Monitoring Committee reviews promotional material for compliance with the provisions of the Code of Conduct, provides relevant advice on current marketing practices and trends to Medicines Australia and, if deemed necessary, submits any complaints as a result of its findings to the Code of Conduct Committee.

Medicines Australia member companies are required to submit to the Committee selected types of promotional material published, distributed or used during a nominated three-month period for the product category under review. The Committee, which includes representatives from the AMA, RACGP, an expert in the therapeutic category under review, and a member of the relevant patient support group reviews this material to determine whether it is compliant with the provisions of the Code of Conduct.

In 2002/2003 the Monitoring Committee reviewed 268 items of promotional material and 22 company websites.

4.5.3 Publication of Outcomes of Code and Monitoring Committee Meetings

- Code of Conduct Committee

Medicines Australia produces an annual report and in interim report (on website) detailing information on all complaints received each year. The summaries of each complaint include the name of the complainant (individual complainant names are not published but registered as 'healthcare professional'), subject company, detail of the complaint, outcomes of the Committee's deliberations and any sanctions imposed by the Committee. This report is available in hard copy and on the Medicines Australia website.

- Code Newsletter

Medicines Australia produces a member newsletter detailing the outcomes of the Code and Monitoring Committee deliberations. Recommendations from the Code and Monitoring Committees and current issues relating to the code are also included. This newsletter is circulated to all member companies.

4.5.4 Training and Education

- Continuing Education Program (CEP)

Medicines Australia's CEP is designed to educate medical representatives to a recognised industry standard. Medicines Australia has long been committed to the quality training of its members' medical representatives. The CEP provides a candidate with formal training to enhance their roles as medical representatives in the pharmaceutical industry.

The program is compulsory for medical representative employed by members of Medicines Australia, and recommended to those who may not be currently employed within the industry but would like to pursue a career as a medical representative.

- Code Specific Education

Medicines Australia undertakes presentations, workshops and meetings for member and non-member companies on the Code and the activities of companies when marketing prescription medicines to healthcare professionals.

In addition to companies, Medicines Australia provides similar services to advertising and PR agencies, conference and event organisers, healthcare professional organisations and health consumer organisations.

In 2002/2003 Medicines Australia presented to some 1500 individuals who represented 53 organisations.

4.6 Therapeutic Goods Advertising Code Council (TGACC)

This section of the report was not included in the original terms of reference but is included for completeness. It gives a summary of educational activities undertaken by the TGACC since the introduction of the current TGAC in April 2000.

Following the gazettal of the TGAC and its launch in Sydney on 6 April 2000, a 'educational roadshow' was taken to Melbourne, Brisbane, Adelaide and Perth to communicate the requirements of the new TGAC and other advertising arrangements. There are no actual figures on the attendance but the TGACC minutes of 8 May 2000 noted that all of the sessions were very well attended.

The TGACC website was launched in October 2000 as a source of information and educational tool. It includes comprehensive information on the advertising requirements for therapeutic goods advertisements directed to consumers and a register of complaints (including the determinations of the Complaints Resolution Panel). It now averages 11,325 visits ('hits') per week.

A two-day seminar was held by the TGACC, in association with the Advertising Federation of Australia, at Curzon Hall in Sydney on 24/25 May 2001 and 149 delegates attended. The seminar was presented in collaboration with industry bodies and the TGA.

Further seminars and exhibits were presented to:

- The Pharmaceutical Society of Australia and the Pharmacy Guild of Australia on 31 July 2001 where 35 people attended.
- A seminar for sponsors was held in Melbourne on 27 February 2002 followed by another for media personnel and consumers the next day. A total of 89 people attended the seminars.
- Twenty members of the Fair Trading Operations Advisory Committee (FTOAC) attended a seminar in April 2002.
- TGACC exhibited at the two-day Integrative Medicines Conference held in Melbourne.
- A seminar was given to 15 staff members from Sudler & Hennessey in Sydney.
- Australian Consolidated Press (ACP Publications) hosted a seminar at the Sheraton on the Park in Sydney on 22 November 2001. There were 45 attendees.

A total of 179 delegates attended TGACC seminars in 2002.

Table 11 summarises the activities of 2003. A total of 391 delegates attended these presentations.

Table 11. Schedule of educational activities for 2003

Location	Date	Audience	Attendees
Sydney	15 April	Advertising agencies	42
ACP Publications	14 May	Media personnel	40
Sydney	19 June	Sponsors	85
Sydney	16 July	Sponsors	58
Melbourne	1 May	Sponsors, media, agencies	67
Brisbane	13 June	Sponsors	32
Adelaide	13 November	Sponsors, media	25
Perth	14 November	Sponsors, media	22
NSW Health consumer protection committee	December	Committee members	20

Table 12 highlights 2004 activities to date and the schedule for the rest of the year.

Table 12. Schedule for 2004

Location	Date	Audience	Attendees
Sydney	19 March	Sponsors	83
Sydney	30 April	Sponsors/media/agencies	45
Melbourne	18 June	Sponsors, media, agencies	76
Brisbane	2 August		
Brisbane	3 August	Pharmacy	
Adelaide	TBC	Sponsors/media/agencies	
Adelaide	TBC	Pharmacy/retailers	
Perth	TBC	Sponsors/media/agencies	
Perth	TBC	Pharmacy/retailers	
Sydney	TBC	Pharmacy/retailers	

4.7 Summary

From the above reports it is evident that all the major industry bodies and the TGACC are actively engaged in ongoing education and monitoring programs. These activities include individual programs conducted under the various codes of practice as well as through collaboration between industry bodies, TGACC and the TGA.

The evidence suggests that these programs contribute to higher levels of awareness and understanding of the controls which are in place in relation to the advertising of therapeutic goods. However, it is also clear, from the earlier findings of this report, that there are sponsors who have failed to benefit from the learning opportunities these systems provide and that further steps might need to be taken to improve compliance with the TGAC with regards to below-the-line advertising.

5 Appendices

Appendix 1 - People consulted during the course of the project

Date	Person	Affiliation
Various	Judith Brimer	TGACC
Various	Sharyn McGregor	TGA
Various	Fiona Cumming	TGA
Various	Juliet Seifert	ASMI
Various	Val Johanson	CHC
Various	Les Dell	DSAA
Various	Kate Howell	Acumen Alliance
Various	Colin Harcourt	APB
Various	Emma Wilson	Media Director, HCG
Various	Anne McIntosh	Database consultant
20 April	John Gooley	OAAA
22 April	Moses Kakaire	Commercial Radio Australia
23 April	Deborah Monk	Medicines Australia
23 April	Catherine Brunskill	ASMI (ASM)
29 April	Pam Longstaff	CAD
5 May	Ruth Ward	CAD
6 May	Fiona Cumming & Christianna Cobbold	TGA
24 May	Jennifer Bergin	Pharmacy Guild
26 May	Chris Arblaster	ASMI
21 June	Christianna Cobbold, Sharyn McGregor, Susan Anido, Kay Hick	TGA
23 June	Allan Crosthwaite	CHC
24 June	Tricia Campbell	CHC (ASM)
25 June	Craig Davies	TGA

Appendix 2 – Tabular data on above the line advertisements (ATL)

Sample	Product	Company	Type	Ther Cat	Media	Size	Format	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total	
A	001	c01	OTC	Allergy & Immune	Television	15 sec	TVC																		
A	002	c02	COM	Skin	Magazine	1/3-p	Print ad																		
A	003	c02	COM	Skin	Magazine	1/3-p	Print ad																		
A	004	c03	OTC	Allergy & Immune	Television	15 sec	TVC																		
A	005	c04	OTC	Skin	Newspaper	1/4-p	Print ad												c						1
A	006	c05	COM	Musculoskeletal	Newspaper	FP	Print ad																		
A	007	c05	COM	General Health	Newspaper	FP	Print ad																		
A	008	c05	COM	Musculoskeletal	Newspaper	1/2-p	Print ad																		
A	009	c05	COM	Alimentary	Magazine	FP	Print ad																		
A	010	c05	COM	Alimentary	Magazine	FP	Print ad																		
A	011	c05	COM	Alimentary	Magazine	FP	Print ad																		
A	012	c06	OTC	Alimentary	Newspaper	1/2-p	Print ad																		
A	013	c06	OTC	Alimentary	Newspaper	1/2-p	Print ad																		
A	014	c06	OTC	Respiratory	Newspaper	1/2-p	Print ad																		
A	015	c06	OTC	Respiratory	Newspaper	1/2-p	Print ad																		
A	016	c06	OTC	Respiratory	Newspaper	1/2-p	Print ad																		
A	017	c07	COM	Musculoskeletal	Magazine	1/2-p	Print ad																		
A	018	c07	COM	Respiratory	Magazine	1/2-p	Print ad																		
A	019	c07	COM	Respiratory	Magazine	1/2-p	Print ad																		
A	020	c08	COM	General Health	Newspaper	1/4-p	Print ad																		
A	021	c08	COM	CNS	Newspaper	1/4-p	Print ad																		
A	022	c08	COM	ENT	Newspaper	1/4-p	Print ad																		
A	023	c09	COM	Genito-urinary	Newspaper	1/2-p	Print ad																		
A	024	c09	COM	Weight management	Magazine	FP	Print ad																		
A	025	c09	COM	Vitamins/Minerals	Newspaper	1/2-p	Print ad																		
A	026	c09	COM	Musculoskeletal	Newspaper	1/2-p	Print ad																		
A	027	c10	COM	Genito-urinary	Magazine	FP	Print ad																		

RATES OF COMPLIANCE OF ADVERTISEMENTS FOR THERAPEUTIC GOODS WITH THE THERAPEUTIC GOODS ADVERTISING CODE

Sample	Product	Company	Type	Ther Cat	Media	Size	Format	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total
A	028	c10	COM	Weight management	Magazine	FP	Print ad																	
A	029	c10	COM	General Health	Magazine	FP	Print ad																	
A	030	c10	COM	Weight management	Newspaper	1/4-p	Print ad																	
A	031	c11	COM	Musculoskeletal	Magazine	FP	Print ad																	
A	032	c12	COM	General Health	Newspaper	1/4-p	Print ad																	
A	033	c12	COM	General Health	Newspaper	1/4-p	Print ad																	
A	034	c13	COM	Musculoskeletal	Newspaper	50-w	Print ad																	
A	035	c13	COM	General Health	Newspaper	50-w	Print ad																	
A	036	c13	COM	CNS	Newspaper	50-w	Print ad																	
A	037	c13	COM	Genito-urinary	Newspaper	50-w	Print ad																	
A	038	c13	COM	Vitamins/Minerals	Newspaper	50-w	Print ad												c,d					2
A	039	c14	COM	Skin	Newspaper	1/4-p	Print ad				1													1
A	040	c15	COM	CNS	Newspaper	1/4-p	Print ad																	
A	041	c15	COM	Genito-urinary	Newspaper	1/4-p	Print ad																	
A	042	c16	COM	Allergy & Immune	Magazine	1/2-p	Print ad																	
A	043	c16	COM	Genito-urinary	Magazine	1/2-p	Print ad																	
A	044	c17	COM	Allergy & Immune	Newspaper	50-w	Print ad							b										1
A	045	c18	COM	Weight management	Newspaper	1/2-p	Print ad																	
A	046	c19	OTC	Analgesia	Television	30 sec	TVC																	
A	047	c19	OTC	Analgesia	Television	30 sec	TVC																	
A	048	c19	OTC	Anti-smoking	Television	30 sec	TVC																	
A	049	c19	OTC	Analgesia	Television	30 sec	TVC																	
A	050	c19	OTC	Alimentary	Television	15 sec	TVC																	
A	051	c19	OTC	Allergy & Immune	Television	30 sec	TVC																	
A	052	c20	OTC	Skin	Magazine	FP	Print ad																	
A	053	c20	OTC	Sunscreen	Newspaper	1/2-p	Print ad																	
A	054	c21	COM	Genito-urinary	Newspaper	1/4-p	Print ad																	
A	055	c21	COM	Genito-urinary	Newspaper	1/4-p	Print ad																	
A	056	c22	COM	Musculoskeletal	Newspaper	1/2-p	Print ad																	
A	057	c22	COM	CNS	Newspaper	1/4-p	Print ad																	
A	058	c23	COM	Musculoskeletal	Magazine	FP	Print ad																	
A	059	c24	COM	Alimentary	Newspaper	1/4-p	Print ad																	
A	060	c25	COM	Musculoskeletal	Newspaper	1/4-p	Print ad																	
A	061	c26	COM	Skin	Magazine	1/2-p	Print ad																	
A	062	c27	COM	ENT	Magazine	1/2-p	Print ad																	

RATES OF COMPLIANCE OF ADVERTISEMENTS FOR THERAPEUTIC GOODS WITH THE THERAPEUTIC GOODS ADVERTISING CODE

Sample	Product	Company	Type	Ther Cat	Media	Size	Format	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total
A	063	c28	OTC	Skin	Magazine	FP	Print ad	NA											c,d					3
A	064	c28	OTC	Sunscreen	Magazine	FP	Print ad																	
A	065	c29	COM	CNS	Magazine	1/2-p	Print ad																	
A	066	c29	COM	General Health	Magazine	1/2-p	Print ad																	
A	067	c29	COM	Genito-urinary	Magazine	1/2-p	Print ad																	
A	068	c30	COM	General Health	Magazine	1/3-p	Print ad																	
A	069	c31	COM	Weight management	Newspaper	FP	Print ad																	
A	070	c31	COM	Weight management	Newspaper	FP	Print ad																	
A	071	c31	COM	Genito-urinary	Newspaper	1/2-p	Print ad																	
A	072	c31	COM	Genito-urinary	Newspaper	1/2-p	Print ad																	
A	073	c32	COM	CNS	Newspaper	50-w	Print ad																	
A	074	c33	COM	Genito-urinary	Newspaper	1/4-p	Print ad																	
A	075	c33	COM	Genito-urinary	Newspaper	1/4-p	Print ad																	
A	076	c34	COM	Genito-urinary	Magazine	FP	Print ad																	
A	077	c35	OTC	Anti-smoking	Television	30 sec	TVC																	
A	078	c35	OTC	Infections/Infestations	Television	15 sec	TVC																	
A	079	c36	COM	Vitamins/Minerals	Magazine	FP	Print advertorial						c											1
A	080	c36	COM	Vitamins/Minerals	Television	45 sec	TVC																	
A	081	c36	COM	Vitamins/Minerals	Newspaper	FP	Print ad																	
A	082	c37	COM	Genito-urinary	Newspaper	1/4-p	Print ad																	
A	083	c38	COM	Vitamins/Minerals	Newspaper	1/2-p	Print advertorial																	
A	084	c39	COM	Genito-urinary	Newspaper	1/3-p	Print advertorial																	
A	085	c39	COM	Genito-urinary	Newspaper	1/3-p	Print advertorial																	
A	086	c40	COM	General Health	Newspaper	100-w	Print ad																	
A	087	c40	COM	Genito-urinary	Newspaper	100-w	Print ad																	
A	088	c40	COM	Genito-urinary	Newspaper	100-w	Print ad																	
A	089	c40	COM	Alimentary	Magazine	1/2-p	Print ad																	
A	090	c41	COM	Allergy & Immune	Magazine	FP	Print ad																	
A	091	c41	COM	Allergy & Immune	Magazine	FP	Print ad																	
A	092	c42	COM	General Health	Magazine	1/2-p	Print ad																	
A	093	c42	COM	Musculoskeletal	Magazine	1/2-p	Print ad																	

Appendix 3 – Tabular data on below the line advertisements (BTL)

Product	Company	Type	Ther. Cat.	Media	Size	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total	
001	c01	OTC	Allergy & Immune	Leaflet	4-p																		
002	c02	COM	Skin	Website	5-p				1														1
003	c02	COM	Skin	Website	3-p						c						c,d						3
004	c03	OTC	Allergy & Immune	Poster	30-w												c,d						2
005	c04	OTC	Skin	Website	2-p												c,d						2
006	c05	COM	Musculoskeletal	Leaflet	6-p	UI																	1
007	c05	COM	General Health	Leaflet	4-p												c,d						2
008	c05	COM	Musculoskeletal	Leaflet	6-p				1								c,d						3
009	c05	COM	Alimentary	Leaflet	6-p												c,d						2
010	c05	COM	Alimentary	Leaflet	6-p												c,d						2
011	c05	COM	Alimentary	Leaflet	6-p												c,d						2
012	c06	OTC	Alimentary	Website	1/2-p																		
013	c06	OTC	Alimentary	Website	FP																		
014	c06	OTC	Respiratory	Website	1/3-p																		
015	c06	OTC	Respiratory	Website	1/3-p																		
016	c06	OTC	Respiratory	Website	1/3-p																		
017	c07	COM	Musculoskeletal	Website	1/3-p												c,d						2
018	c07	COM	Respiratory	Website	FP												c,d						2
019	c07	COM	Respiratory	Website	FP												c,d						2
020	c08	COM	General Health	Website	FP												c,d						2
021	c08	COM	CNS	Website	FP												c,d						2
022	c08	COM	ENT	Website	FP												c,d						2
023	c09	COM	Genito-urinary	Leaflet	4 p DL	UI																	1
024	c09	COM	Weight management	Brochure	2-p												c,d						2
025	c09	COM	Vitamins/Minerals	Brochure	1/2-p												c,d						2
026	c09	COM	Musculoskeletal	Leaflet	6-p DL			i									c,d						3
027	c10	COM	Genito-urinary	Website	50-w												c,d						2
028	c10	COM	Weight management	Website	50-w												c,d						2
029	c10	COM	General Health	Website	50-w	UI											c,d						3
030	c10	COM	Weight management	Website	50-w		a										c,d						3

RATES OF COMPLIANCE OF ADVERTISEMENTS FOR THERAPEUTIC GOODS WITH THE THERAPEUTIC GOODS ADVERTISING CODE

Product	Company	Type	Ther. Cat.	Media	Size	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total
031	c11	COM	Musculoskeletal	Leaflet	6 p DL				1													1
032	c12	COM	General Health	Website	1-p												c,d					2
033	c12	COM	General Health	Website	1-p												c,d					2
034	c13	COM	Musculoskeletal	Website	FP												c,d					2
035	c13	COM	General Health	Website	11/2-p	UI											c,d					3
036	c13	COM	CNS	Website	2-p	UI			1						1	1	c,d					6
037	c13	COM	Genito-urinary	Website	4-p	UI	a									1	c,d					5
038	c13	COM	Vitamins/Minerals	Website	4-p		a										c,d					3
039	c14	COM	Skin	Leaflet	4 p DL							b										1
040	c15	COM	CNS	Website	1/2-p												c,d					2
041	c15	COM	Genito-urinary	Website	1/2-p												c,d					2
042	c16	COM	Allergy & Immune	Website	FP	UI											c,d					3
043	c16	COM	Genito-urinary	Website	FP												c,d					2
044	c17	COM	Allergy & Immune	Website	10-p		i				a						c					3
045	c18	COM	Weight management	Leaflet	4 p DL																	
046	c19	OTC	Analgesia	Poster	20-w																	
047	c19	OTC	Analgesia	Leaflet	4 p DL																	
048	c19	OTC	Anti-smoking	Shelf talker	30-w																	
049	c19	OTC	Analgesia	Poster	30-w																	
050	c19	OTC	Alimentary	Website	30-w												c,d					2
051	c19	OTC	Allergy & Immune	Other																		
052	c20	OTC	Skin	Press Release	FP																	
053	c20	OTC	Sunscreen	Press Release	FP																	
054	c21	COM	Genito-urinary	Website	FP																	
055	c21	COM	Genito-urinary	Website	FP																	
056	c22	COM	Musculoskeletal	Website	FP	UI											c,d					3
057	c22	COM	CNS	Website	FP	UI									1		c,d					4
058	c23	COM	Musculoskeletal	Website	5-p		i										c					2
059	c24	COM	Alimentary	Website	50-w												c,d					2
060	c25	COM	Musculoskeletal	Website	20-w												c,d					2
061	c26	COM	Skin	Website	2-p												c					1
062	c27	COM	ENT	Leaflet	4-p DL												d					1

RATES OF COMPLIANCE OF ADVERTISEMENTS FOR THERAPEUTIC GOODS WITH THE THERAPEUTIC GOODS ADVERTISING CODE

Product	Company	Type	Ther. Cat.	Media	Size	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total
063	c28	OTC	Skin	Shelf talker													c,d					2
064	c28	OTC	Sunscreen	Shelf talker													c,d					2
065	c29	COM	CNS	Website	FP						a				1		c,d					4
066	c29	COM	General Health	Website	FP						a						c,d					3
067	c29	COM	Genito-urinary	Website	FP	UI	c				a						c,d					5
068	c30	COM	General Health	Brochure	8-p	UI	b				c		1			1	c,d					7
069	c31	COM	Weight management	Website	50-w		a										c,d					3
070	c31	COM	Weight management	Website	50-w												c,d					2
071	c31	COM	Genito-urinary	Leaflet	6 p DL	UI									1	1	d					4
072	c31	COM	Genito-urinary	Leaflet	6 p DL	UI											d					2
073	c32	COM	CNS	Website	6-p						c						c,d					3
074	c33	COM	Genito-urinary	Website	3-p												c,d					2
075	c33	COM	Genito-urinary	Website	5-p																	
076	c34	COM	Genito-urinary	Brochure	12-p																	
077	c35	OTC	Anti-smoking	Brochure	8-p																	
078	c35	OTC	Infections/Infestations	Website	3-p												c,d					2
079	c36	COM	Vitamins/Minerals	Brochure	6-p DL	UI										1						2
080	c36	COM	Vitamins/Minerals	Website	1/2-p												c,d					2
081	c36	COM	Vitamins/Minerals	Website	1/2-p												c,d					2
082	c37	COM	Genito-urinary	Website	2-p												c,d					2
083	c38	COM	Vitamins/Minerals	Brochure	12 -p											1	d					2
084	c39	COM	Genito-urinary	Website	3-p						c						c,d					3
085	c39	COM	Genito-urinary	Website	3-p												c,d					2
086	c40	COM	General Health	Leaflet	6-p												d					1
087	c40	COM	Genito-urinary	Website	50-w												c,d					2
088	c40	COM	Genito-urinary	Website	50-w												c,d					2
089	c40	COM	Alimentary	Website	FP												c,d					2
090	c41	COM	ENT	Brochure	20-p												c,d					2
091	c41	COM	Allergy & Immune	Brochure	20-p	UI			1								c,d					4
092	c42	COM	General Health	Leaflet	2-p																	
093	c42	COM	Musculoskeletal	Website	2-p		i				c		1				c,d					5

Appendix 4 – Tabular data on collected samples of advertisements (CS)

Sample	Product	Company	Type	Therap Category	Material	Format	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total
C	001	c01	OTC	Infections/Infestations	Leaflet	6 p DL		g				c						d					3
C	002	c01	OTC	Infections/Infestations	Leaflet	6 p DL		g				c						d					3
C	003	c02	COM	General Health	Leaflet	6-p																	
C	004	c02	COM	CNS	Leaflet	4-p	UI			1								d					3
C	005	c02	COM	Musculoskeletal	Leaflet	6-p												d					1
C	006	c02	COM	General Health	Leaflet	8-p	UI			1								d					3
C	007	c02	COM	General Health	Leaflet	10-p				1								d					2
C	008	c02	COM	Genito-urinary	Leaflet	6-p				1								d					2
C	009	c03	OTC	Musculoskeletal	Leaflet	4 p DL																	
C	010	c03	OTC	Respiratory	Leaflet	4 p DL																	
C	011	c03	OTC	Alimentary	Leaflet	4 p DL																	
C	012	c03	OTC	ENT	Leaflet	4 p DL												d					1
C	013	c03	OTC	CNS	Leaflet	6 p DL	UI			1								d					3
C	014	c03	OTC	General Health	Leaflet	4 p DL												d					1
C	015	c03	COM	General Health	Leaflet	4 p DL												d					1
C	016	c03	COM	Infections/Infestations	Leaflet	4 p DL																	
C	017	c03	COM	General Health	Leaflet	6 p DL																	
C	018	c03	COM	General Health	Leaflet	4 p DL																	
C	019	c03	COM	General Health	Leaflet	4 p DL																	
C	020	c03	COM	General Health	Leaflet	4 p DL	UI																1
C	021	c03	COM	General Health	Leaflet	4 p DL																	
C	022	c04	OTC	ENT	Catalogue	FP												d					1
C	023	c05	COM	Vitamins & minerals	Leaflet	4 p DL																	
C	024	c05	COM	Vitamins & minerals	Leaflet	4 p DL																	
C	025	c06	OTC	Infections/Infestations	Leaflet	2-p					1												1
C	026	c07	COM	Weight management	Leaflet	6 p DL		a,c														1	3
C	027	c07	COM	Weight management	Leaflet	6 p DL	UI	a														1	3
C	028	c07	COM	Weight management	Leaflet	6 p DL																1	1
C	029	c07	COM	CNS	Leaflet	6 p DL	UI	a									1	d					4
C	030	c07	COM	CNS	Leaflet	6 p DL	UI	a,g								1		d					5
C	031	c07	COM	CNS	Leaflet	6 p DL	UI	a								1		d					4
C	032	c07	COM	Skin	Leaflet	6 p DL		a,i				c						d					4
C	033	c08	OTC	Sunscreen	Leaflet	6 p DL												c,d					2
C	034	c08	OTC	Sunscreen	Leaflet	6 p DL												c,d					2
C	035	c08	OTC	Infections/Infestations	Leaflet	6 p DL												d					1

RATES OF COMPLIANCE OF ADVERTISEMENTS FOR THERAPEUTIC GOODS WITH THE THERAPEUTIC GOODS ADVERTISING CODE

Sample	Product	Company	Type	Therap Category	Material	Format	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total	
C	036	c09	COM	Vitamins & minerals	Brochure	16 p																		
C	037	c10	COM	Musculoskeletal	Leaflet	6 p DL		a																1
C	038	c10	COM	Musculoskeletal	Leaflet	6 p DL		a																1
C	039	c10	COM	Vitamins & minerals	Leaflet	6 p DL	UI	a																2
C	040	c11	COM	Genito-urinary	Brochure	12-p												d						1
C	041	c12	COM	Alimentary	Leaflet	4 p DL		b		1							1							3
C	042	c13	OTC	General Health	Catalogue	1/2-p												c,d						2
C	043	c13	OTC	ENT	Catalogue	FP																		
C	044	c13	OTC	Skin	Catalogue	FP																		
C	045	c13	OTC	ENT	Catalogue	1/2-p																		
C	046	c13	OTC	Skin	Catalogue	1/2-p												d						1
C	047	c13	OTC	Allergy & Immune	Catalogue	FP																		
C	048	c14	COM	Skin	Leaflet	4 -p		i		1		c						d						4
C	049	c15	COM	Allergy & Immune	Leaflet	4 p DL				1		b						d						3
C	050	c16	COM	Vitamins & minerals	Catalogue	FP																		
C	051	c16	COM	General Health	Catalogue	FP																		
C	052	c16	COM	General Health	Catalogue	FP																		
C	053	c16	COM	Weight management	Catalogue	FP																		
C	054	c16	COM	Vitamins & minerals	Catalogue	FP																		
C	055	c16	COM	Vitamins & minerals	Catalogue	FP																		
C	056	c17	OTC	Allergy & Immune	Giant pack																			
C	057	c17	OTC	Allergy & Immune	Poster	A1																		
C	058	c17	OTC	ENT	Poster	A3												d						1
C	059	c17	OTC	Skin	Poster	A3												d						1
C	060	c18	COM	General Health	Leaflet	8-p	UI			1		c						d						4
C	061	c19	COM	Vitamins & minerals	Leaflet	12-p						c						d						2
C	062	c20	COM	CNS	Leaflet	4 p DL	UI																	1
C	063	c20	COM	Alimentary	Leaflet	8 p DL	UI																	1
C	064	c21	COM	General Health	Catalogue	20-p												c,d						2
C	065	c21	COM	Alimentary	Catalogue	20-p	UI											c,d						3
C	066	c21	COM	General Health	Catalogue	20-p												c,d						2
C	067	c21	COM	General Health	Catalogue	20-p	UI	b,i										c,d						5
C	068	c21	COM	Alimentary	Catalogue	20-p	UI											c,d						3
C	069	c21	COM	General Health	Catalogue	20-p												c,d						2
C	070	c21	COM	Alimentary	Catalogue	20-p	UI											c,d				1		4

Appendix 5 – Tabular data on direct sellers’ advertisements (DS)

Sample	Product	Company	Type	Category	Type	Size	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total
D	001	c01	COM	CNS	Catalogue	FP	UI			1		c				1							4
D	002	c01	COM	General Health	Leaflet	2-p																	
D	003	c01	COM	CNS	Leaflet	2-p																	
D	004	c01	COM	Infections/Infestations	Catalogue	1/2-p						c											1
D	005	c01	COM	Musculoskeletal	Leaflet	2-p																	
D	006	c02	OTC	Sunscreen	Catalogue	FP												c,d					2
D	007	c02	COM	Respiratory	Catalogue	50-w												e					1
D	008	c02	COM	Vitamins & minerals	Catalogue	30-w												c					1
D	009	c02	COM	General Health	Catalogue	30-w												c					1
D	010	c03	COM	General Health	Leaflet	FP	UI											c,d					3
D	011	c03	COM	Vitamins & minerals	Leaflet	FP		c		1								c,d					4
D	012	c03	COM	Vitamins & minerals	Leaflet	2-p					1						1	c,d					4
D	013	c04	COM	Alimentary	Website	1/2-p												c,d					2
D	014	c04	COM	Weight management	Website	2-p												c,d					2
D	015	c04	COM	General Health	Website	1/2-p												c,d					2
D	016	c05	COM	General Health	Website	1/2-p												c,d					2
D	017	c06	COM	General Health	Catalogue	FP												c					1
D	018	c06	COM	Vitamins & minerals	Catalogue	FP												c					1
D	019	c06	COM	General Health	Catalogue	FP												c		1			2
D	020	c06	COM	General Health	Catalogue	FP												c					1
D	021	c06	COM	ENT	Catalogue	FP												c					1
D	022	c07	COM	Alimentary	Website	FP												c,d					2
D	023	c07	COM	CNS	Website	FP												c,d					2
D	024	c07	COM	ENT	Website	FP	UI											c,d					3
D	025	c07	COM	Alimentary	Website	FP	UI											c,d				1	4
D	026	c07	COM	General Health	Website	FP												c,d					2
D	027	c08	COM	Vitamins & minerals	Website	5-p	UI							1		1	1	c,d					6
D	028	c09	COM	Allergy & Immune	Training materials	6-p												c,d					2
D	029	c09	OTC	Sunscreen	E-mail	50-w												c,d					2
D	030	c09	COM	Vitamins & minerals	Catalogue	FP												c,d					2

RATES OF COMPLIANCE OF ADVERTISEMENTS FOR THERAPEUTIC GOODS WITH THE THERAPEUTIC GOODS ADVERTISING CODE

Sample	Product	Company	Type	Category	Type	Size	4.1.1	4.1.2	4.1.3	4.2	4.3	4.4.1	4.4.2	4.5	4.6	5.1	5.2	6.2	7.1.2	7.1.3	7.2	7.3	Total	
D	031	c09	COM	General Health	Catalogue	1/2-p												c,d					2	
D	032	c09	COM	CNS	Catalogue	1/2-p												c,d					2	
D	033	c10	COM	General Health	Catalogue	50-w												c,d					2	
D	034	c10	COM	Vitamins & minerals	Catalogue	50-w												c					1	
D	035	c10	COM	Vitamins & minerals	Catalogue	50-w												c					1	
D	036	c10	COM	Vitamins & minerals	Catalogue	FP												c,d					2	
D	037	c10	COM	CNS	Catalogue	FP												c					1	
D	038	c10	COM	CNS	Catalogue	FP												c,d					2	
D	039	c11	COM	General Health	Website	FP	UI					a						c,d					4	
D	040	c11	COM	General Health	Website	FP	UI					a					1	c,d					5	
D	041	c11	COM	General Health	Website	FP		i				a					1	c,d					5	
D	042	c11	COM	CNS	Website	FP	UI	c				a,c					1	c,d					7	
D	043	c11	COM	CNS	Website	FP	UI	i				a					1	c,d					6	
D	044	c12	COM	CNS	Website	30-w												c,d					2	
D	045	c13	COM	General Health	Website	2 FP		c										c,d					3	
D	046	c13	COM	Alimentary	Website	FP												c,d					2	
D	047	c13	COM	Alimentary	Website	FP												c,d					2	
D	048	c13	COM	General Health	Website	FP				1							1	1	c,d					5
D	049	c14	COM	Vitamins & minerals	Website	FP												c,d					2	
D	050	c14	COM	Vitamins & minerals	Website	FP												c					1	