Foundation for Effective Marketing and Governance (FEMAG)

Essential elements for effective regulation of therapeutic goods and services claims

Seminar on Advertising of Therapeutic Goods and Services (and its Regulation)

University of Sydney, Health Law Centre
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Therapeutic goods advertising regulation

In Australia all advertisements and generic information provided about Therapeutic Goods directed to the public must comply with provisions of the Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and the Therapeutic Goods Advertising Code (TGAC).

Advertising must also conform to the Australian Consumer Law.

The history of the advertising Code goes back almost 40 years. The Code was originally developed by the first TGACC which had been established in the 1970s by the Media Council of Australia (MCA). The MCA administered the operation of the TGACC as well as the revision and maintenance of the Code. The Code was authorised by the Trade Practices Tribunal in 1988, and gained a degree of legal underpinning in February 1991 when parts of it were picked up by the Therapeutic Goods Act 1989.

The MCA advised the Australian Competition and Consumer Council (ACCC) in September 1996 that it would cease operation at the end of that year. This left the Code Council and the Code orphaned.

Following the demise of the MCA scheme, two key industry associations, the Proprietary Medicines Association of Australia (now the Australian Self-Medication Industry) and the Nutritional Foods Association of Australia (now the Complementary Healthcare Council), formed a collegiate with a view to taking over the administration of the Code Council and getting authorisation of the Code by the ACCC.

However, this arrangement would have applied only to members of the two associations and not to all advertisers of therapeutic goods. As a result, the collegiate embarked on a different route that would provide a system applicable to all.

This was achieved through a range of amendments (Amendment 400) to the Therapeutic Goods Act and Regulations in December 1997. Amendment 400 provided for the establishment of a Therapeutic Goods Advertising Code Council, a Complaints Resolution Panel and the formal approval of mainstream print advertisements for therapeutic goods.

A major review of all advertising arrangements in 1999 resulted in the development of a principles-based code and the expansion of the approval and complaints processes to include other forms of therapeutic goods advertising. Generic information about therapeutic goods is included.

Code Council's key responsibilities are to:

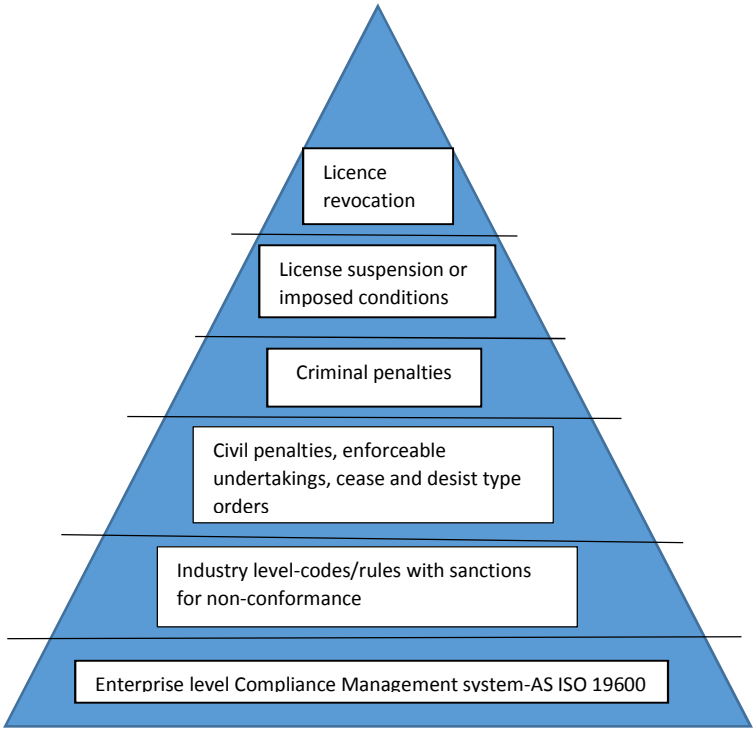
- ensure that the Therapeutic Goods Advertising Code is current, relevant and reflects community values and standards (the Code is discussed in more detail below)
- ensure a level playing field for all advertisers
- make recommendations to the Minister about:
    - uniform standards in approval processes and advertising
    - appeals about approvals decisions
    - submissions for exemption to use restricted representations
    - the application of public interest criteria
    - policy advice.

Purpose of this paper

The purpose of this paper is to set out essential elements for regulating therapeutic goods and services claims with the twin purposes of ensuring consumers' health and safety by putting more emphasis on market-based and market-sensitive means of conformance but, at the same time, having a safety net whereby those who either deliberately flout the law or who have inadequate compliance management systems can be dealt with quickly and, where appropriate, with serious penalties to ensure industry or professional-wide compliance with the law.

Background

Some years ago academics John Braithwaite and Ian Ayers suggested in their book *Responsive Regulation: Transcending the deregulation debate*[1] a compliance model which was elegantly represented as a compliance pyramid. Below is a pyramid which uses their pyramid as a basis for a model for regulating therapeutic goods and services.



The basic idea behind the pyramid is that the top level drives the bottom level where the majority of compliance occurs. Put another way, if an enterprise making a therapeutic claim wants to avoid the harsher penalties at the top of pyramid then it needs to have a compliance management system in place at the enterprise level to reduce the risk of non-conformance of relevant laws/regulations/ codes covering therapeutic goods and services relevant to its particular business. In short, this is a carrot and stick approach.

[1] Ayres, Ian and John Braithwaite (1992) "Responsive Regulation: Transcending the deregulation debate". New York: Oxford University Press

The bottom of the pyramid: Enterprise level compliance management systems

The compliance profession and compliance ideas have been growing exponentially in the last few years. It is now recognised that compliance with laws, regulations or rules is more likely to occur if an enterprise uses a compliance management system. The recent release of the international standard on compliance management systems (ISO 19600) is the embodiment of this development.

Before explaining the features of a compliance management system it is important to focus on some drivers as to why an enterprise should undertake establishment of a compliance management system. These include:

- ***Due diligence defence*** where if an organisation is able to demonstrate that it has taken all reasonable steps to introduce and inculcate compliance measures, such actions will serve only to strengthen that organisation's due diligence defence
- ***Reduction or elimination of negative exposure,*** which may otherwise involve the media, shareholders or other stakeholders, the market, regulators
- ***Reputation protection,*** such as irretrievable damage because of the public image of poor management practices
- ***Losing money,*** that can come about through fines, legal fees and most damaging of all, damages sought by affected parties
- ***Enhancing risk management systems*** where a small investment in setting up a compliance system can insure/minimise disproportionately high financial and reputational damage.

It is now well established that compliance with laws doesn't 'just happen', but that some essential features must exist for conformance to occur. A framework setting out these essential elements can be found in Attachment A.

Top management commitment

It goes without saying that top management must 'walk the talk' when it comes to supporting therapeutic goods and services claims regulatory compliance. This means that they should oversight compliance through such things as regular and robust reporting, taking an *active* interest in compliance and practicing what they preach. They also need to satisfy themselves that their enterprise's regulatory risks have been identified and continue to be, so that controls have been developed, implemented and monitored to manage these risks.

Someone responsible for driving compliance

Someone in the organisation has to be ultimately responsible for designing, implementing and maintain the compliance system, and in particular, undertaking risk assessment and allocating compliance responsibilities to the relevant parts of the business. Large organisations these day have a senior manager designated as a Compliance Manager whereas mid to small organisations would have someone senior whose responsibilities include these roles.

Regulatory risk assessment and controls

Assessing **all** therapeutic goods and services claims regulatory compliance risks is also critical. No two organisations are the same so risk assessment has to reflect and be customised to the particular enterprise. This is not only a one-off exercise but also needs to be reviewed regularly to cover emerging risks or changed circumstances. The appropriate business unit that has responsibility for managing the relevant controls needs to be identified, and procedures to manage identified risks developed with the unit, implemented and monitored for adherence.

One of the major ways to manage therapeutic goods and services claims is through use of a checklist along the lines set out in Attachment B.

Compliance plan

Having a therapeutic goods and services claims Regulatory Compliance Plan that sets timelines – stipulating when important compliance processes must be carried out during the year – means that critical compliance actions are carried out on a regular basis.

Documentation

A documentation system to record compliance-related activities is important to demonstrate due diligence in compliance.

Access to expert advice

Being able to demonstrate such a practice can only strengthen a company's due diligence defence, particularly where the issue is not clear cut.

Training and education

Quite often training, mentoring and/or coaching needs to be undertaken so that relevant staff are aware of their responsibilities and how they need to be carried out.

Monitoring

Regular and documented monitoring to ensure adherence to procedures is an important maintenance and due diligence feature.

Other forms of monitoring could include:

- the person responsible for overall compliance of the system undertaking unannounced spot checks to ensure procedures are being followed
- ensuring mandatory attendance at training
- involving in-house auditors to undertake audits that procedures designed to control high risk matters are being conformed to.

Reporting systems

Reporting systems such as complaints handling and whistleblowing systems need to be established to assist in detecting non-conformance and are appropriate forms of monitoring. Excellent guidance on setting up a complaints management system can be found in *Guidelines for complaint management in organizations* (AS/NZS 10002-2014) and for a whistleblowing system in *Whistleblower Protection Programs for Entities* (AS 8004-2003).

Rectification procedures

Procedures should be in place to undertake an analysis of why a compliance failure has occurred, and rectification action aimed at preventing a reoccurrence should be undertaken.

One way of ensuring compliance within an organisation is to design, implement and maintain a compliance management system. Assistance with this task can be found in the recently published international standard on compliance ISO 19600 *Compliance Management Systems – Guidelines.*

The second bottom tier of the pyramid: Industry level-codes/rules – Self regulatory initiatives

Industry wide self-regulation can make a contribution to compliance but it needs to meet some essential elements to be effective. For example, a point that is often overlooked by many in government and industry is that industry can often lack regulatory skills and culture that are necessary if industry is to 'self-regulate'.

Self-regulation or voluntary initiatives need nurturing and assistance in the formative stages.

In Australia, a code of conduct model has been developed which has had some degree of success in delivering public benefit outcomes. These models have nearly all been drafted with some government intervention or oversight. Some even have representatives from the relevant government agencies as observers. For example, the Australian Pharmaceutical Manufacturers Association has an observer from the Therapeutic Goods Administration on its Compliant Handling Committee. This does two things. It allows the relevant regulator to have a 'window' on the scheme to satisfy itself that the scheme is working in the public interest, but it also allows the agency to lodge complaints with the body – an indication of its confidence in the scheme's ability to deliver.

The successful models have certain common features that are discussed below.

Virtually all of the successful models of codes involve industries that are well organised, well resourced (from the 'big end of town') and have a sound association structure with good coverage of the industry.

On the other hand, there is not a good track record in that section of industry involving small to medium operators who generally have a fragmented association structure with inadequate and insufficient industry coverage as well as inadequate resources.

The key criteria for effective codes include:

Addressing consumer concerns

To be effective in addressing consumer concerns a code needs to have rules which address common complaints and concerns about industry practices, and which set performance standards for participants. Such rules should address specific stated problems and not be written as broad, general principles.

The code should set out in its objectives clearly stated reasons why the code was established and what intended outcomes it sets out to achieve.

Consultation

To have any credibility at all there needs to be consultation with the appropriate consumer/ community/user groups and appropriate regulatory/government agencies. It goes without saying that the industry members themselves need to be consulted.

Sometimes the use of a reference committee can be a cost effective way of having all relevant interests come together and debate and agree on appropriate standards.

Typically consultative devices include user/consumer/community:

- consultation in the drafting of the code
- involvement in the code administration and review

- involvement in complaints handling where appropriate.

Code administration

Unless there is a body responsible for ensuring the implementation and the ongoing administration of the scheme then its success in delivering fair trading outcomes is severely limited. A code administration body needs to be established and its existence and operations written into the code document itself so that it becomes part of the overall code. Typically the responsibilities of administration bodies will include:

- monitoring and reporting on compliance
- obtaining from members adequate finance for administering the code and preparing budgets and financial reports
- ensuring publicity for the code
- making provision for employee awareness of the code
- imposing agreed sanctions on members for breaches of the code
- conducting periodic reviews of the effectiveness of the code and its procedures, and recommending amendments if necessary
- preparing annual and other reports on the operation of the code.

Transparency

Industry based code schemes aimed at delivering fair trading outcomes need to contain appropriate consumer/user representation on the administration committee, and where appropriate, in complaints handling. In some instances, representation by the appropriate regulatory authority on the code administration body can serve as a means of the regulatory body putting forward a public interest view. Such representation provides transparency to the scheme by providing a 'public window' on its operations which ensures that the industry group will be acting in the broader public interest.

Coverage

The effectiveness of any code will only be as good as the amount of coverage the code has of the relevant industry for which it is aimed. Where codes are being used as an alternative to government legislation some form of mandating legislation may be required to ensure industry wide coverage where this cannot be achieved by voluntary means.

Complaints handling

The code should include provisions to allow for complaints to be lodged and then to be handled by signatories. Performance criteria for effective complaints handling should form part of the self-regulatory scheme. Of particular importance is that conduct that has adverse impacts on consumer health should be stopped as soon as possible.

In-house compliance

The code's administration body needs to ensure that each participant has some form of in-house compliance management system to ensure compliance with the code. It can also assist compliance at this level with advice and training.

Sanctions and other powers for non-compliance

Commercially significant sanctions will be necessary to achieve credibility with, and thus compliance by participants and also engender consumer confidence in the code/self-regulatory scheme. The

self-regulatory body also needs to have the power to stop conduct that has an adverse impact on consumer health.

Independent review of complaints handling decisions

The code should also provide for a review mechanism where a member of the public or an industry member is dissatisfied with the outcome or the way the complaint was dealt with or the sanctions imposed at first instance.

Consumer awareness

Unless consumers are aware of the code and its contents the code will be ineffective in achieving its fair trading aims. The code provisions themselves should incorporate mechanisms designed to ensure that consumers and other relevant groups are made aware of the terms of the code and its complaints handling provisions.

As codes give consumers some measure of assurance that a trader strives to operate by established standards of conduct, there could be benefit in publishing a list of traders that have adopted a consumer code/charter and who are deemed to abide by it.

Industry awareness

In many cases a code fails to operate effectively, not because its principles and procedures are inadequate, but because employees or industry members are either unaware of the code or fail to follow it in day-to-day dealings. A provision in the code requiring employees and agents to be instructed in its principles and procedures is therefore essential. This is a task which needs to be overseen by the code administration body.

Data collection

Data collection is important, not only from a reporting point of view, but as a valuable source of market information about the origins and causes of complaints, and therefore to enable identification of systemic and recurring problems which need addressing by industry members.

Monitoring

Regular monitoring of codes for compliance is essential, not only to ensure the desired outcomes, but to ensure that ethical members complying with the code are not disadvantaged.

Accountability

Annual reports on the operation of the code should be produced by the code administration committee, allowing for periodic assessment of the scheme's effectiveness.

Review

A code should provide for regular reviews to ensure that the standards incorporated are meeting current community expectations and that the code is working effectively.

Competitive implications

Codes should avoid being written in such a way that they have a negative impact on competition. Where it is considered necessary for the success of the operation of the code to include anti-competitive provisions, there needs to be a transparent public benefit justification process.

Performance indicators

Performance indicators should be developed and implemented as a means of measuring the effectiveness of the code's operation. Examples include:

- a high level of awareness of the code amongst participants and consumers
- easy accessibility of the code to consumers
- decreased level of complaints received on issues the code is designed to address
- otherwise meeting the stated objectives of the code
- high visibility and easy accessibility of complaints handling mechanisms, including quick response times
- effective in-house code compliance mechanisms are in place by participants.

The third level tier of the pyramid: Civil remedies

If the systems above are applied effectively then there should be high level of compliance with relevant therapeutic goods and services claims regulation. That said there will always be risk takers or those with less than robust compliance management systems who are in breach of relevant laws and regulations.

Therapeutic goods advertising has a critical dimension which many other forms of advertising do not have, and this is that it involves consumer health and safety. This means that there are a number of essential elements/indicia that a system must have if it is to be effective in protecting consumer health and safety.

Stopping the conduct

As it now stands, an entity making a misleading claim can 'game' the system due to it taking some time for the processes to be exhausted. This can particularly be the case where the product is sold on a seasonable basis (e.g. sunscreen). Timeliness (i.e. stopping the conduct) is critical particularly where there is or is likely to be an adverse impact on consumer health or safety.

An appropriate tool from the regulatory toolbox would be an *injunction* for a court sanctioned order.

Access to compensation

Where consumers have been affected by misleading claims they should have the right to claim damages. This is an important driver for entities to make sure that they have a robust compliance and QA system to reduce the risks of misleading claims being made.

Appropriate tools from the regulatory toolbox would include private rights of action to sue for misleading claims or the product liability provisions of the *Competition and Consumer Act.*

Demonstrated adequate levels of compliance

The first section of this paper covers what would now be considered the essential elements of a therapeutic goods claims compliance management system. A system like this may go some way (a) to avoid the risk of misleading claims being made and (b) as a means of proving due diligence to the regulators and, ultimately, the courts.

Punishment for persistent and/or deliberate wrongdoing

Innovative approach to regulatory action

This is the level where intervention of the regulators such as the Australian Competition and Consumer Commission (ACCC) and the Therapeutic Goods Administration (TGA) currently have a role.

If the ACCC and the TGA bodies work cooperatively in much the same way as the ACCC currently does with the state and territory fair trading authorities this could be an efficient and effective way to deal with misleading therapeutic claims.

Both organisation setting out therapeutic claims as an enforcement priority and signalling that they are working cooperatively would send clear signals to industry players that the risks of having an ineffective or no compliance system is not worth the risks.

Civil remedies

One of the advantages of this level is that the burden of proof is, on the balance of probabilities, a lesser burden than the near beyond reasonable doubt for criminal offences.

Case Study: ACCC action regarding Nurofen

In proceedings commenced by the Australian Competition and Consumer Commission, the Federal Court has found that Reckitt Benckiser (Australia) Pty Ltd (Reckitt Benckiser) engaged in misleading conduct in contravention of the Australian Consumer Law by representing that its Nurofen Specific Pain products were each formulated to treat a specific type of pain, when the products are identical.

The Nurofen Specific Pain product range consists of Nurofen Back Pain, Nurofen Period Pain, Nurofen Migraine Pain and Nurofen Tension Headache.

The court found that Reckitt Benckiser made misleading representations on the packaging of each Nurofen Specific Pain product, and on its website www.nurofen.com.au (link is external), that each product:

- was formulated to treat a particular type of pain; and
- solely or specifically treated a particular type of pain.

In fact, each product contains the same active ingredient, ibuprofen lysine 342mg, and is no more effective at treating the type of pain described on its packaging than any of the other Nurofen Specific Pain products.

The emphasis at this level needs to be on taking corrective action quickly. Remedies that are currently available under the *Competition and Consumer Act* are:

Civil pecuniary penalties: A person who is found to have breached certain provisions of the CCA, such as the prohibition against false or misleading representations, may be liable to pay a **civil** pecuniary penalty of up to $1.1 million for companies and $220,000 for individuals. A civil penalty is a financial penalty or fine imposed by the court and is designed to deter the business and others from breaching the law. A penalty may only be imposed by the court once it has found that the person has breached the ACL at the civil standard of proof. This means that the person must be proved to have breached the ACL on the balance of probabilities that the conduct was more likely to have occurred than not.

Substantiation notices: Under section 219 of the Australian Consumer Law the ACCC has the power to issue a substantiation notice to a person asking them to provide information which verifies claims which they make in advertisements or promotions of goods or services. This would be a particularly useful power when misleading therapeutic claims are made.

An injunction (a court order)*:* Ordering the business to stop the conduct that is breaking the law.

Compensation orders: In most instances, a person suffering loss or damage as a result of a breach of the Australian Consumer Law (ACL) can obtain a compensation order against the business or individual involved in the breach. In some cases, an ACL regulator may also seek a compensation order on behalf of such persons. Compensation orders can be made on whatever terms the court thinks necessary to compensate those suffering loss or damage.

Enforceable undertakings: For example, ordering the liable business to establish a **compliance or training program** for staff to reduce the risk of further contraventions, publish corrective advertising or disclose specified information.

Disqualification orders: For certain breaches of the ACL, the Federal Court may order that a person be disqualified from managing a business for such a period as it considers appropriate.

Infringement notices (penalty notice): If the ACCC *has reasonable grounds to believe* that a business has made a false or misleading representation, it may issue an infringement notice, which in effect is a fine.

Adverse publicity orders: This is an order directing a business (or individuals) to disclose information and publish an advertisement about their breach. This order may only be made in respect of some breaches of the ACL.

Safety warning notices

Of particular relevance to therapeutic goods are specific product safety related issues such as the ***product liability and recalls provisions***.

Under the Australian Consumer Law's ***product liability laws***, consumers who suffer loss or damage because of safety defects in a manufacturer's goods when supplied in trade or commerce can:

- take the manufacturer to court (a court can award compensation to cover the loss or damage)
- make a complaint to a consumer protection agency, which may take action on the consumer's behalf.

'Loss' and 'damage' can include:

- injuries to the person making the claim, or injuries or death to another individual
- economic loss caused by damage to, or destruction of another good, land, a building or a fixture.

A product has a safety defect if its safety is not what the community is generally entitled to expect. While the level of safety will vary from case to case, it is ultimately for the court to determine whether a product has a safety defect. There are various factors the court will take into account when making its determination, including:

- how and for what purposes the product has been marketed
- the product's packaging
- the use of any mark in relation to the product
- instructions for, or warnings about assembling and using the product
- what might reasonably be expected to be done with the product
- the time when it was supplied.

A good will not necessarily be considered to be safe just because it complied with a Commonwealth mandatory standard.

A business's quality assurance system, design, production, record keeping and marketing procedures as well as customer information material can promote the safety of its products with consumers.

The role of the bottom of the pyramid to work in this space was summed up succinctly by Justice Edelman in *ACCC v Woolworths,* when he stated that "The penalties I have imposed are designed in broad terms to achieve specific *and general deterrence by requiring vigilance concerning quality management procedures to ensure the accuracy of representations and effective procedures for the recall or withdrawal of products and the notification of the ACCC. This is particularly so where products can affect consumer safety* [emphasis added] and the person deals in the sale of large volumes of consumer products."

The fourth level tier of the pyramid – Criminal remedies

This is used where breaches are deliberate or systemic. The maximum criminal and civil penalties (fines) for making false or misleading representations are $1.1 million for businesses and $220,000 for individuals.

The fifth and sixth level tiers of the pyramid – Imposing conditions on, suspending or revoking a licence

These actions can only be applied where the regulatory system involves licensing, and would again be available to the regulator to use where there has been a deliberate, systemic breach. Publicity about such action by the regulator sends a clear message to others in the industry to make sure that they have robust compliance management systems in place.

Attachment A: Framework of a Compliance Management System

Structural

Board/top management involvement
Adequate resources
Compliance policy
Risk assessment
Allocation of responsibility
Appointment of a Compliance Officer/Manager
Compliance Committee
Management supervision
Compliance calendar/compliance plan
A system of documentation of all compliance material

Operational

Operating procedures
Education and training
Regular communications designed to secure compliance
Performance appraisal
Access to expert advice

Maintenance

Monitoring systems
Reporting systems
Compliance failures identified, their causes analysed and rectification action taken

Attachment B: Marketing Compliance Checklist

Why have a checklist?

The *Competition and Consumer Act* (CCA) prohibits misleading and deceptive conduct. Other regulations such as the *Therapeutic Goods Act* and the *Therapeutic Goods Code* set out more specific rules governing advertising and promotion of therapeutic goods and services.

The CCA does not require an intention to mislead. Enterprises will be liable even if they make innocent mistakes.

The overall test is: will the target audience be misled? If the message is targeted at the public at large, the overall test is: will the message mislead the average person in the street? Whether the principle not to mislead is broken depends on the overall impression created in the minds of the target audience.

What is it for?

The purpose of this checklist is to ensure that an enterprise's advertising and promotional materials do not breach the CCA and other regulations. This checklist is designed to be used in the preparation of all marketing material (including TV, radio, point of sale material and website) and for all promotions.

How do I complete it?

The object of the checklist is for all relevant questions to be answered 'yes'. Where the answer is 'no', then the matter needs to be fixed.

What do I do next?

This checklist needs to be completed for **all** advertising and promotional activity. Once the checklist is completed, it needs to be signed at the bottom, attached to all material relevant to the marketing activity and then forwarded to the reviewer so that they can consider this checklist alongside the marketing material.

COMPETITION AND CONSUMER ACT AND THERAPEUTIC GOODS REGULATIONS QUESTIONS	**YES**	**NO**	**N/A**
Misleading Conduct (the target audience)			
Have you considered your target audience and the overall impression your promotion/advertising will have?			
Is the overall impression of the material correct?			
Does the medium through which you are conveying your message adequately disclose important terms and conditions in their 'real world' situation? (e.g. TV, radio or billboards may not be suitable for complex offers with detailed qualifications)			

COMPETITION AND CONSUMER ACT AND THERAPEUTIC GOODS REGULATIONS QUESTIONS	**YES**	**NO**	**N/A**
Are you sure you have not left out or hidden any important information that the target audience may need?			
Is every word true and accurate?			
Are you sure you have not omitted any significant information?			
Is there written evidence to support any statements of fact?			
Are any representations on future matters based on accurate historical data that is recorded in writing?			
Have you ensured that any factual material or data relied on is not out of date?			
Have you exaggerated or been overly optimistic?			
Is the 'Headline' on the material consistent with the content?			
Are goods or services offered as "free" actually free?			
Prizes			
Are all statements made about the prize(s) true including the: ▪ Nature and value of the prize(s)? ▪ Place of origin of the prize? ▪ Availability of prizes as and when promised?			
Is the prize accurately described?			
Do you have the intention of providing the offered gifts or prizes as offered?			
Have you checked that the prize/bonus draw prize will be available as long as tickets are on sale?			
Has the prize been purchased/arranged to ensure that it is available as described in the terms and conditions?			
Terms & Conditions			
Have all significant terms and conditions been included in the material?			
Have you brought the significant terms and conditions (e.g. eligibility for entry, call costs to enter) to the customer's attention prior to the purchase of an entry?			
Are the terms and conditions accurate, understandable and concise?			

COMPETITION AND CONSUMER ACT AND THERAPEUTIC GOODS REGULATIONS QUESTIONS	**YES**	**NO**	**N/A**
Are the terms and conditions available at the time the promotion starts?			
Do the terms and conditions state the correct closing date/dates of draw and/or promotional period?			
Do the terms and conditions set out who is included or excluded from entry (e.g. Mail Sales)?			
Do the terms and conditions state the conditions of entry?			
Fine Print			
Is there a fine print qualification in the material?			
Is it consistent with the overall impression of the material?			
Is it sufficiently prominent and proximate to the statement it is qualifying?			
Is it easy to read (i.e. minimum 8 point font size)?			
Do the terms and conditions set out the conditions of the competition generally (e.g. whether entrants have to partake in any activity and if so, the terms of that activity)?			
Website			
Is the information on the web site up-to-date?			
Are disclaimers prominently displayed on the web page, or accessible via a link?			
Miscellaneous			
Have you obtained approval to make any representations about a sponsorship, approval or affiliation (if any)?			
Have you made any statement that the enterprise adheres to certain codes and standards? If so, ensure that the enterprise complies with these codes/ standards (e.g. Therapeutic Good Codes or any Australian Standard).			

Checker I have completed this checklist and attached the marketing material (where possible). To the best of my knowledge the marketing material does not present any CCA or other therapeutic goods and services regulations risks identified above.

Name: _____

Signed:_____Date: _____

Reviewer I have reviewed this checklist and the marketing material and confirm that to the best of my knowledge the material does not present any CCA or other therapeutic goods and services regulations risks identified above.

Name: _____

Signed:_____Date: _____

Approver I approve the marketing material.

Name: _____

Signed:_____Date: _____