Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance on applying the 2021 Advertising Code rules

Part 2 – Application of the Code

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About the Therapeutic Goods Advertising Code

The Therapeutic Goods Advertising Code (the Code) is the cornerstone of the therapeutic goods advertising regulatory framework. It sets out the requirements for advertisements about therapeutic goods in the public domain.

It is an offence under the *Therapeutic Goods Act 1989* (the Act) for a person to advertise therapeutic goods by any means or cause the advertising of therapeutic goods by any means that does not comply with the Code.

Whoever publishes or broadcasts an advertisement for therapeutic goods **may** be held responsible for it even in circumstances where the advertising material has been provided by another party.

Consumers in the market for therapeutic goods are choosing goods to use in relation to their health. The legal requirements imposed on advertisements about therapeutic goods, including the requirement to use certain mandatory statements, protect the potential vulnerability of these consumers. It is important that advertisements support informed decision making by containing accurate, balanced and sufficient information that is not misleading or likely to result in consumers delaying health professional advice.

Part 1 of the Code sets out the objects of the Code which are to ensure that advertisements about therapeutic goods:

- promote their safe and proper use
- do not mislead or deceive the consumer or create unrealistic expectations about product performance
- support informed health care choices
- are not inconsistent with relevant current public health campaigns.

This guidance should be read with the Code and its Explanatory Statement. It provides further information about the interpretation and application of the Code provisions.

The Code imposes legal requirements for advertising therapeutic goods in addition to those set out in the Australian Consumer Law in recognition of the potential vulnerability of consumers who are choosing products for their health.

Part 2 – Application of the Code

Section 5 - When the Code applies

Section 5 of the Code sets out the circumstances in which the Code applies. The Code applies to advertisements about therapeutic goods other than advertisements specified in section 6. See When the Code rules do not apply.

Section 3 of the Act defines advertise in relation to therapeutic goods as:

> *'any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods.'*

Intention is assessed not only by what the person responsible for the content intends (direct intent), but also by what the average consumer would reasonably view as being intended by the content (indirect intent). This means that if members of the public would reasonably consider that the information is intended to promote the use or supply of the identified goods, then the TGA would be likely to consider it an advertisement.

More information about what constitutes an advertisement about therapeutic goods is available in the guidance: Activities that represent advertising.

In applying the Code to an advertisement about therapeutic goods, the following factors are considered:

- its likely impact on a reasonable person (i.e. an average member of the public with sound judgement) to whom it is directed
- its total presentation and context including the target audience, where there is one.

Example: target audience

A print advertisement for an intraocular lens (a medical device) intended for the correction of age-related presbyopia targets people with age related vision problems. The advertiser considers the reduced vision capacity of the target audience.

The advertiser displays all mandatory statements and health warnings taking into consideration the potential vision impairment of the advertisement's audience in ensuring the required statements are prominently displayed or communicated according to the Code's requirements. For more information see Guidance on applying the 2021 Advertising Code rules - Part 4 and Part 5.

Total presentation and context

The total presentation and context of an advertisement means all elements of the advertisement that contribute to the message conveyed to the target audience, including:

- the words and images used
- the claims that are made – noting the Code applies to ALL claims (therapeutic claims and non-therapeutic claims) in an advertisement
- the advertising medium

- other material in proximity to the advertisement that is likely to be seen by a viewer of the advertisement.

For example, an advertisement on social media will be considered in the context of comments from third parties that are associated with the advertisement. More information on this is available in the TGA social media advertising guide.

Example – Impact of images on the meaning of claims that are made

A complementary medicine is indicated for the *relief of mild joint aches and pains*.

An advertisement for the product includes an image of a person with excessively swollen and red joints. It is unlikely the person suffers with mild joint aches and pains.

In considering the total presentation of the advertisement it is likely the advertisement would be seen to be promoting the medicine for the relief of severe joint pain and would therefore be unlikely to be compliant with the Code.

Example – Impact of other material in proximity to the advertisement

An advertisement for a fish oil product (a listed complementary medicine) makes the claim *supports eye health*. The advertisement is on the same page as an article about promising research about the use of fish oil in the management of attention deficit disorder in children.

Consideration must be given as to whether the placement of the advertisement (its context) will influence the likely consumer take-out message of the advertisement and whether it will be taken to be representing that the advertised fish oil may be of benefit in children with attention deficit disorder.

Section 6 - When the Code does not apply

Section 6 of the Code sets out the circumstances in which the Code **does not** apply.

The Code rules do not apply to:

- **An advertisement directed exclusively to any person mentioned in section 42AA of the Act.** This includes health professionals such as medical practitioners, psychologists, dentists and pharmacists. For more information see Advertising to health professionals.
- **Advertisements that are part, or otherwise comprise a public health campaign**. These are campaigns that are conducted, approved or funded by the Commonwealth, state, territory or local governments. These campaigns aim to protect, promote and improve the health and wellbeing of the Australian public.
- **Advertisements made in accordance with** the Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022. For more information see Communicating about COVID-19 vaccines.
- **Genuine news** that is published or broadcast in any medium by a broadcaster, datacaster, the SBS, the publisher of a print edition of a newspaper or magazine.

Additionally, the advertising of prescription-only and certain pharmacist only medicines to the public is prohibited; however, price information for these medicines can be advertised, with the Code setting out the conditions under which this may occur.

- section 6 also provides that the Code rules, other than Part 9, do not apply to advertisements that only contain **price information** about registered goods that contain a substance in schedule 3, 4 or 8 to the current Poisons Standard (but not a substance included in Appendix H of the current Poison Standard. For more information see Part 9 – Price information.

Part 3 – General requirements

Part 3 of the Code specifies the general requirements for advertisements about therapeutic goods in the public domain.

Section 8 – Accuracy

Advertisements must be accurate, balanced, not be misleading and only contain substantiated claims

An advertisement about therapeutic goods must:

- **be accurate**, including by:
  - being objectively truthful and free from errors
  - only containing information that is current and correct
- **be balanced**, including by providing:
  - fair and unbiased claims
  - providing information about contra-indications or precautions where relevant to enable consumers to balance any claims with other important information about the good – for example an advertiser may choose to include a statement that the advertised good is not suitable for a certain population group
- **not mislead or likely to mislead consumers**, including by ensuring that the advertisement:
  - does not giving a false impression about the product, including for example, its ingredients, composition or design, benefits of use and safety profile etc
  - does not contain information that is easily misinterpreted and likely to lead consumers to an error of judgement, for example by using statistical data that is difficult to interpret
  - does not omit important information about the product
  - does not contain exaggerated or irrelevant claims

and must:

- only contain **information that has been substantiated by the advertiser** prior to the advertisement being published or otherwise disseminated.

Example – Misleading by omitting important information

A diagnostic imaging business advertises their services and the imaging devices they use. The advertisement states that the x-ray imaging device they use *produces 5 times less radiation than other common imaging devices*.

- While this claim may be accurate, the advertisement does not provide information explaining that the amount of radiation produced by all these devices is extremely small and well within safe limits.
- The claim is likely to mislead consumers because it omits important information that even the larger dose of radiation from other x-ray imaging devices is not considered harmful to the human body.
- Additionally, the advertisement compares one therapeutic good or service to another in a way that implies that the other devices may be harmful.

Example – Misleading by making inaccurate and false claims

Anaya claims in her advertising that her therapeutic good is 'all natural'. The advertising does not provide an explanation for these claims.

The product label includes ingredients such as almond milk and parsley extract but also includes a range of known synthetic preservatives and stabilisers.

- The use of ‘all natural’ in this advertising is misleading because the product contains ingredients that are not from a source that a consumer would understand as being ‘natural’.

For more information see promoting your product as natural.

Example – Misleading and unbalanced information

An advertisement for a home-use defibrillator uses the claim *‘8 in 10 cardiac arrests occur in the home.’*

- The advertisement is likely to mislead in the absence of information including that:
  - the defibrillator will only work if someone is there to use it on the person having the heart attack
  - a home-use defibrillator can only be effective in certain heart attacks (i.e. ones that have a shockable rhythm)
- Additionally, by not explaining that CPR may also need to be administered, the advertisement presents an unbalanced impression about the advertised device.
- Representations which refer to ‘cardiac arrests’ in advertisements for therapeutic goods are ‘restricted representations’ which must not be used without prior approval by, or permission from, the TGA.

Example – misleading and unbalanced information

An advertisement for an over-the-counter medicine indicated for pain relief associated with a range of conditions including 'mild osteoarthritis' is published in a magazine. The medicine is for use by adults and children over 12 years.

- ✗ An image in the advertisement depicts red and swollen joints of a woman who is sitting with a young child – this may misleadingly give consumers the impression that the advertised medicine is indicated for osteoarthritis that is not 'mild' and that the medicine is suitable for use in children less than years old.

Example – Making an unsubstantiated non-therapeutic claim

A social media influencer endorses an eczema cream and makes the claim that it is the *'cream most frequently chosen by Australian consumers'.*

- ✗ The influencer has not substantiated this claim (noting that all claims in advertisements must be substantiated before use and not just claims relating to therapeutic use).

For more information see Testimonials and endorsements in advertising and the TGA social media advertising guide.

Advertisements must be consistent with the products ARTG entry

Advertisements about products included in the Australian Register of Therapeutic Goods (ARTG) must not be inconsistent with the indication or intended purpose of the product as it is recorded on the ARTG.

- Indications or intended purposes do not need to be replicated exactly. They may be reworded or joined together to improve comprehension or presentation provided the meaning and intent is not changed.
- Qualifying or clarifying information attached to the therapeutic claim may be used if it is substantiated. For example, "For the relief of the symptoms of hay fever' [the indication recorded in the ARTG] without causing drowsiness [qualifying information]." Note: where therapeutic goods are exempt from inclusion in the ARTG, the advertising must not be inconsistent with the label, or the package insert of the good.

Example – Inconsistency with the ARTG entry

A pharmacy advertises a listed medicine with the ARTG indication: 'relief of eye strain' and 'relief of visual fatigue'.

The pharmacy advertises the medicine with the claim: *'DELAY THE NEED FOR PRESCRIPTION LENSES – this product relieves eye strain and visual fatigue'*

- ✗ This claim is not consistent with the medicine's ARTG entry.
- ✗ The permitted indication for listed medicines, 'reduce visual fatigue', expressly states that the product presentation must not imply or refer to vision correction. For more information see the Therapeutic Goods (Permissible Indications) Determination.

When it becomes aware of its likely non-compliance, the pharmacy changes the claims to:

✓ Working at a computer can strain the eyes – [medicine x] may help to relieve visual fatigue.

Section 9 - Safe and proper use

The Code requires that advertising must support the safe and proper use of therapeutic goods.

Advertisements must not represent goods as safe or effective in all cases

Advertisements about therapeutic goods must NOT, either expressly or by implication, represent the advertised goods to be:

- safe or without side-effects
- effective in all cases or a guaranteed cure
- infallible, unfailing, magical, or miraculous.

Therapeutic goods can cause different reactions in people and will have side-effects for a proportion of users. They are not always safe or effective for everyone.

The Code helps to ensure consumers are not inappropriately influenced by advertisements. Advertisers should avoid words or images that would give the impression that the safety and efficacy of the advertised goods is guaranteed or remarkable.

Example – Representing a product as safe

An advertisement for a barrier cream regulated as a Class I medical device contains a claim that is consistent with the intended purpose of the device, contains the required mandatory statements and in every other way is apparently compliant with the Code.

However, a testimonial included in the advertisement states: *I love this cream. I'm comfortable knowing it is safe for my daughter's skin and therefore for her little body*.

× The testimonial implies the advertised product is safe and must be removed by the advertiser.

Example – Representing the product as miraculous

Beans Pty Ltd advertises their combination multi-vitamin and mineral product as 'the holy grail of good health'.

× This claim is likely to give the reasonable consumer the impression that the product is miraculous or infallible.

Advertisements must not cause alarm or distress

Advertisements must NOT:

- cause undue alarm, fear or distress
- contain a representation to the effect that harm could occur if the product is not used (unless the representation has been permitted or approved under the Act).

Advertising should not take advantage of people's concern for their health by using fearmongering in advertisements. This type of advertising does not support rational and informed decision making by consumers.

Example – Using language that could cause fear and distress

An advertisement for a home use defibrillator makes the claim: *Did you know 9 out of 10 heart attacks occur in the home?*

- ✗ This is a type of fearmongering.
- ✗ The claim is also a 'restricted representation' because it refers to 'heart attack'. A restricted representation must not be used in an advertisement unless it has been approved or permitted by the TGA.

Example – Using language that could cause fear and distress

An advertisement for 'diabetic footwear' makes the claim: *60% - 70% of diabetes patients have mild to severe forms of foot nervous system damage and nearly 1 in 5 of people living with diabetes are at risk of developing diabetic foot complications which can result in amputation*

- ✗ This is playing on the vulnerability of people with diabetes. While the claim may be accurate it may cause fear or distress.
- ✗ Representations which refer to 'diabetes', 'foot nervous system damage' and 'amputation' are 'restricted representations' which must not be used in advertisements for therapeutic goods without prior approval or permission from the TGA.

Example – Suggesting harmful consequences could result from the therapeutic good not being used

A company advertises its new winter vitamin range along with the following statement: *Purchase our new winter specific vitamins to boost your immune system and avoid catching this year's deadly flu.*

- ✗ This claim, by referring to 'this year's deadly flu' suggests consumers' lives could be saved by using the advertised product.

Advertisements must not encourage inappropriate use

Advertisements about therapeutic goods must NOT contain statements, pictorial representations or designs that:

- are inconsistent with the directions or instructions for use for the good on the label, consumer medicine information, or patient information leaflet of the goods
- suggest consumers delay seeking medical attention or use the advertised product in favour of using a treatment prescribed by a medical practitioner
- exaggerate the good's efficacy or performance
- encourage consumers to use therapeutic goods inappropriately or excessively
- compare the goods with other therapeutic goods, classes of goods or therapeutic services which suggests that comparators are harmful or ineffective. For more information see Product and service comparisons.

It is important that information in advertisements does not conflict with information about the advertised good that is on the label or in other instructional documents. These requirements extend to testimonials, which themselves must comply with the Code. For more information see Testimonials and endorsements in advertising - Part 6.

Example – Inconsistency with the label, encouraging inappropriate use

The sponsor of a registered over-the-counter medicine advertises the medicine in a way that suggests the medicine may be used by the general population. Images of a family with children are included in the advertisement.

× The advertised medicine is not for use in children – the ad encourages inappropriate use and is inconsistent with the directions for use on the label of the medicine.

Example – Encouraging excessive use and exaggerating the good's efficacy

A claim is made in an advertisement for Beans Caff-Tabs that this medicine will '*help you study all night long*'.

× To stay awake 'to study all night long' a person would be likely to need to take more than the recommended daily dose.

Imagery contains a vibrant university student obtaining their degree.

× This claim could generate unrealistic consumer expectations resulting in excessive or inappropriate use of the advertised product.

Example – Encouraging inappropriate use

An advertisement for Beanscreen SPF 50+ (not water resistant) claims that it will '*protect you all day long*'.

× This claim is inconsistent with the label instructions to reapply frequently and after swimming or towelling.

The advertisement contains images of people in the water.

× This could give consumers the impression that the non-water-resistant sunscreen could provide suitable protection in the water, thereby encouraging inappropriate use.

Example – Encouraging self-medication rather than seeking health professional advice

An advertisement for a complementary medicine indicated for pain relief makes the claim: *Fed up with headaches that never seem to go away?*

- ✗ This statement could result in a consumer attempting to self-manage a condition for which they may require timely health professional diagnosis or treatment.

Example – Suggesting consumers use the advertised products rather than use a prescribed treatment

An advertisement for Beans Decompress Vitamins claims: *This vitamin can assist in lowering your blood pressure. John found it so effective he no longer needs the blood pressure medication his doctor prescribed.*

- ✗ This claim promotes the advertised good as an alternative to a prescribed treatment. This may lead to a consumer failing to use prescribed medicines.
- ✗ Additionally, 'lowering blood pressure' is not an indication that is currently permitted for a listed medicine.

Product and service comparisons

Comparative advertising identifies a competing product and makes or implies certain claims about the competing product. Consumers may be particularly susceptible to comparative advertising for therapeutic goods. They may have insufficient knowledge to comprehend the subtleties of this type of advertising and their lack of knowledge can easily be exploited.

An advertisement which compares the advertised good with one or more competitor or other goods must not use comparative advertising that:

- suggests that the comparator goods or services are harmful or ineffectual
- makes broad comparisons like *'higher strength'* or *'better absorbed'* unless it is clear to the audience which goods are being compared
- uses superlatives to describe a therapeutic good, such as '*the best*' or '*works fastest*', that suggest a comparison to all other goods or services unless supported by evidence against other products in the marketplace.

In accordance with section 8 of the Code, comparative advertising must:

- be factual and substantiated
- not mislead the consumer about the benefits of the advertised good in comparison with the other products or services including by taking advantage of consumers' lack of knowledge
- be fair and balanced:
  - comparative advertising should not discredit other products either directly or by implication.

Example – Comparative advertising

An advertisement for Beans Organic Tampons contains a long list of chemical ingredients included in competitor's tampons along with the claim “Buy Beans and avoid the chemicals’.

- This type of advertising suggests the comparator goods are harmful.

Example – Comparative advertising

An advertisement for the oral medicine BeansAid contains the claim that ‘*BeansAid is a natural anti-inflammatory that works as well as other anti-inflammatory medicines such as cortisone, without the risks'.*

- This advertisement implies that the comparator good, cortisone, is harmful, by referring to its risks.
- Additionally, oral cortisone and certain topical cortisone are prescription medicines. Advertisements must not contain a reference to a prescription medicine unless the reference has been permitted by the TGA.

Section 10 - Consistency with public health campaigns

Section 10 of the Code requires that advertising must not be inconsistent with a current public health campaign.

Public health messages are based on considerable research and expert advice. The objective of this requirement is to ensure that the advertising of therapeutic goods does not undermine or otherwise diminish the message contained in government public health campaigns.

Government priorities in public health messaging change depending on needs within the community (for example, during ‘flu season’) and developments in health policy, while others are more likely to remain constant (for example, ‘sun safety’). However, a 'current' campaign does not necessarily have to be actively promoted at the time of the advertisement. If the campaign was part of an active public health strategy and it is reasonably known (or ought to be known) that it was in effect, then it may be considered a public health campaign for the purposes of the Code.

Advertisers should be aware of current public health campaigns so they can:

- ensure any planned advertisements are not inconsistent with these important health and safety messages
- identify any existing advertising that may be inconsistent with new campaigns.

Example – Not consistent with current public health campaign

An advertisement for a vitamin and mineral supplement contains the claim: *Fruit and veggies are expensive – stay within your food budget and get all the vitamins and minerals you need!*

- ✗ This advertising is not consistent with government health campaigns relating to eating a wide variety of fruit and vegetable daily.
- ✗ The advertisement is also not compliant with regulation 6B and Schedule 2 of the Therapeutic Goods Regulations 1990 which prohibits representations that vitamins can replace a balanced diet.

Section 11 - Scientific or clinical representations

Section 11 of the Code sets out the requirements for advertisements that make scientific or clinical representations, or when the advertisement contains an explicit or implied reference to scientific or clinical literature.

Section 11 requires that scientific or clinical representations used in advertisements about therapeutic goods are:

- consistent with the broader body of evidence relating to the product
  - relying on or referencing a study which is inconsistent with the body of evidence is likely to be misleading
  - ensuring the conclusions of a study are not exaggerated or misrepresented.
- clearly explained in language that is easily understood by consumers
  - scientific or medical 'jargon' can be difficult for consumers to understand
  - the use of statistical data can be difficult for consumers to analyse or interpret correctly
  - scientific terms for health conditions may not be understood by consumers
- cited in a way that identifies the researcher and financial sponsor of the research where the advertiser should reasonably know that information
- cited in a way that enables consumers to access the study or research
  - citations can be tailored to suit the specific media where the advertisement appears
  - footnotes and embedded links may be adequate.

Section 11 of the Code does not apply to:

- labels of therapeutic goods
- consumer medicine information
- instructions for use
- patient information leaflets.

This exemption only applies to the display of printed information such as a physical label that is attached to or supplied with the goods. For example, the exemption does not apply to advertisements that contain images of the good (e.g. pack shots) where all or part of the label is visible.

What are scientific or clinical representations?

The term 'representation' is broad and includes therapeutic and non-therapeutic claims about the product, warnings, precautions and the name of the product, including those conveyed through statements, pictures and videos.

Representations that state or imply that scientific or clinical literature is available to support a claim are likely to give consumers the impression that the effectiveness of the advertised product has been proven through rigorous clinical or scientific studies. If this is not the case, the claim is misleading.

In the context of advertising therapeutic goods to the public, a 'scientific' or 'clinical' representation is one that:

- references supporting scientific or clinical research
  - describes outcomes that are observed in a clinical setting, such as 'clinically demonstrated to...' or 'clinically proven to…', or ‘studies show....'
- uses scientifically framed claims or terminology that is not generally used in the everyday language of the audience to whom the advertisement is directed
  - describes the scientific process or mode of action that occurs when goods are used for therapeutic use
- contains scientific (and pseudoscientific) terminology
  - this covers concepts such as diseases, treatments and medicines that do not appear in the everyday language of the audience to whom the advertisement is directed.

An implied reference to scientific or clinical research occurs when a consumer would reasonably expect a statement or claim to be supported by specific research results. An implied scientific or clinical representation may be used in association with a statement of the therapeutic good's indication or intended purpose. Examples include:

- ‘‘as referred to in Journal XYZ…….’.
- ‘starts to work in 10 minutes’
- ‘7 out of 10 people had clearer skin within one week’.

How to cite scientific or clinical studies

Advertisements that make a scientific or clinical representation must contain a citation to the study or research supporting the claim.

- If one study substantiates all claims made, then citing only that study is sufficient.

- If one study substantiates only one claim, but multiple claims are made, then the studies relied on to substantiate those other claims must also be cited. This can be via a list that is external to the advertisement for example via an internet link.
- If multiple studies are being relied on to substantiate the same claim, it is sufficient to cite the highest quality source of evidence provided it is a balanced representation of the available literature.

Citations are **not** required for the indications or intended purpose of the advertised good as these are recorded on the ARTG. However, advertisers may use citations to supporting scientific or clinical studies to provide extra support for a claim. These citations must comply with Section 11 of the Code.

When citing scientific or clinical studies to validate claims made in advertising you must:

- identify the studies with sufficient and unambiguous information so consumers can locate and read it for themselves
  - at a minimum, this can be done by providing:
    - the author, study name, publication location or full publication name, date of publication, page number or article reference number online
    - internal identifying information for internal data or unpublished studies when cited
    - a hyperlink to the study.
- identify the researcher and the financial sponsor of the research
- clearly disclose the source of the funding for the study (and whether the study is wholly funded by that source or partially funded including, for example, through the provision of a study drug), where the advertiser knows or ought to reasonably know that information
  - most studies require funding and so where that money comes from should be communicated in advertising
  - this is particularly important when the source of funding is, or is associated with, the therapeutic good's sponsor, manufacturer, ingredient manufacturer or advertiser.

Referencing scientific or clinical studies to support claims made in advertisements gives credibility to the claims, so it is important that studies are used correctly.

In accordance with section 8 of the Code, the use of a scientific or clinical representation must:

- be factual and substantiated
  - the supporting studies must meet the required standards of evidence (please refer to the TGA's published evidence guidelines for listed medicines, assessed listed medicines, over-the-counter (OTC) medicines, medical devices)
  - the results should demonstrate a clinically meaningful (not just a statistically significant) outcome. In this context 'clinically meaningful' means that the user of the good should have a reasonable expectation of experiencing the change to their disease, condition or defect as documented in the supporting studies

- not mislead consumers about the quality and relevance of the evidence
  - the conclusions of the study must be relevant to the claim(s) made in the advertisement.

A study is unlikely to be supportive of a scientific or clinical representation if, for example:

- it has not been peer reviewed
- it has not been replicated
- it has an insufficient number of participants
- it uses inadequate inclusion and exclusion criteria for participants
- it has an inadequate trial protocol or study design, as may be the case if the study is not 'blinded' (where relevant):
  - in blinded studies, the study participants are not aware if they are receiving the trial medicine or a placebo, in double blinded studies, the study participants and the people running and analysing the study do not know which participants are receiving placebo and which are receiving the trial medicine itself.

In addition, the representation and the supporting scientific and clinical evidence must be consistent with the broader body of evidence applicable to the goods. For example:

- if there are 50 well conducted studies that point to the same conclusion, and one study that came to the opposite conclusion, then that one study is inconsistent with the broader body of evidence and must not be cited as support for that opposing conclusion.

Claims based on in-vitro or 'test-tube' evidence or animal studies (i.e. studies that are not clinical studies) are **not acceptable** to support clinical claims in advertising. This applies for all advertisements in the public domain, even those in which it is stated 'not available for purchase by the general public'.

Data on file

Scientific or clinical representations may be supported by unpublished scientific studies or in-house data held by the product sponsor or manufacturer.

If such a study is referenced in an advertisement:

- the term 'data on file' does not provide sufficient information to allow consumers to access the study, however:
  - advertisers can use data on file if they are willing to make it available to consumers, e.g. "Data on file – ABC study 123/2021; available from… [website / link /phone]" so that consumers are given adequate information to enable them to access the research if they wish to do so.
- the citation must be sufficiently detailed to allow verification that a copy provided to the public is the underpinning study for the advertised claim.

Advertisers must not cite research in an advertisement that is not available to the consumer for reasons of confidentiality.

Identifying a financial sponsor

Many scientific journals now require and publish the financial sponsor of a study. In-house studies will also have this information available from the owner of the studies. Where these studies are cited in an advertisement, the financial sponsor must also be disclosed.

Where the sponsor of a scientific study is a government department or agency, the advertiser must take care to ensure that endorsement of the therapeutic good by that government agency is not implied.

Example

The National Health and Medical Research Council funds research into the use of Vitamin D in the development of eyes in children. Advertisements for Beans Vitamin D gummies includes a scientific citation:

> *Scientific studies show that regular exposure to sunlight or vitamin D in children 8 years and younger can have a preventative effect from developing short-sightedness later in life.*

The advertisement includes the citation:

> ** Theodore Bean [name], Vitamin D study in children [Name of study] and 2022, Journal of Beanie Therapeutics, www.URL.com.au [publication details] funded by the National Health and Medical Research Council.*

✓ Merely stating the name of the source of funding for the study is unlikely to imply government endorsement of the good.

✗ However, reframing the claim as "NHMRC studies[#] show that…" might imply that the NHMRC endorses the product and would need careful consideration within the context of the advertisement.

Section 12 - Advertising to children

Section 12 of the Code prohibits advertising of therapeutic goods which is directed to children under the age of 12 years.

It is not responsible for advertisers to target children in advertisements for therapeutic goods.

In general, children are unlikely to have the sufficient knowledge or reasoning required to choose a therapeutic good or make informed and responsible healthcare choices. Nor are they sufficiently aware to understand the persuasive nature of advertising.

There are, however, exceptions in relation to advertising certain therapeutic goods to children 12 years and over, consistent with their increasing independence from adults.

An advertisement may be directed to children aged 12 years and over if:

- the product is mentioned in Annexure 1 of the Code and the conditions (if any) are complied with, and
- the product does not contain a substance included in Schedule 2, Schedule 3, Schedule 4, or Schedule 8 of the Poisons Standard.

The products included in Annexure 1 are considered low risk goods that older children could generally purchase and safely use without supervision from an adult.

Section 12 does not apply to product labels, including where the labels contain images or graphics to make a product more attractive to children or clearly indicate that the product is suitable for children such as characters, colouring, fonts and other designs.

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