



Using scientific or clinical claims (representations) in therapeutic goods advertising

Understanding the requirements of Section 15 of the Therapeutic Goods Advertising Code (No.2) 2018

It's important to understand how to correctly use scientific or clinical claims when advertising therapeutic goods to the public.

This information is for those involved in the marketing of therapeutic goods who use scientific or clinical representations or claims in advertisements by:

- using scientifically framed claims (i.e. scientific claims)
- citing research studies (explicitly or impliedly), or
- using scientific (and pseudoscientific) terminology.

Understanding the requirements

All claims made in advertisements for therapeutic goods must comply with the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code (No.2) 2018 (the Code). Advertisers must only use claims that are substantiated.

At times advertisers may seek to use scientific claims to add credibility or depth to their advertisement. However, consumers may not have the skills and knowledge to critically evaluate these types of claims and may find it challenging to understand complex scientific or medical terminology.

Section 15 of the Code requires that:

- **scientific claims** are consistent with the body of relevant evidence (relying on or referencing a study which is inconsistent with the body of evidence is misleading)
- **scientific terminology** is communicated in a way that is readily understood by the target audience for the advertisement (for example, the use of statistical data can be difficult for consumers to analyse correctly and scientific terms for health conditions may not be understood by consumers), and

- **research studies** are cited in a way that identifies the researcher and financial sponsor of the research, where the advertiser should reasonably know that information, and in a way that enables consumers to access the study. Citations can be tailored to suit the specific media where the advertisement appears. Footnotes and embedded links **may** be adequate. What is important is that the consumer can readily locate these details.

Section 15 of the Code does not apply to a label or consumer medicine information or a patient information leaflet.

What are scientific or clinical representations?

The term 'representation' is broad. Representations can include warning statements, the name of a product and claims about the product (including those conveyed through pictures and videos). A 'scientific' or 'clinical' representation is one that:

- uses scientific or medical terminology that is not generally used in the everyday language of the audience to whom the advertisement is directed,
- or
- necessarily and overtly relies on scientific or clinical research (such as 'clinically demonstrated to ...' or 'studies show...').

Scientific studies

Scientific studies constitute research through the systematic collection, interpretation and evaluation of data. Scientific studies can include studies conducted on animals.

Clinical studies

The type of research most relevant to therapeutic goods is 'clinical' research. Clinical studies involve people and can be observation studies or clinical trials. Clinical trials are conducted to determine the safety and efficacy of therapeutic goods. Using clinical studies to substantiate claims (by way of citing such studies) will result in the advertisement being non-compliant with the Code if the studies do not meet certain standards (such as being peer reviewed, containing sufficient subject numbers, using adequate 'blinding' and being consistent with the broader body of evidence).

A clinical study may only be used to support a claim where the conclusions are relevant to the claim and demonstrate a clinically meaningful (not just a statistically significant) outcome.

Claims based on in-vitro ('test-tube') evidence or animal studies are not acceptable to support clinical outcome claims in advertising.

What is an 'implied' citation to scientific or clinical literature?

An implied citation to scientific or clinical studies occurs when a consumer would expect a claim to be supported by specific research results. An implied citation may be a stand-alone claim or may be used in association with a statement of the therapeutic good's indication or intended purpose.

Examples include:

- clinically trialled...
- lab studies show... [indication or intended purpose]
- starts to work in less than 30 minutes

High-level claims that imply a citation to scientific or clinical literature, such as a claim that a product has been 'clinically proven', are likely to give consumers

the impression that the effectiveness of the advertised product has been proven beyond doubt through rigorous clinical/scientific studies. If this is not the case, the claim is misleading. Otherwise, a reference to the study or studies needs to be provided in the advertisement in which the claim is used.

Advertisers may use citations to scientific or clinical studies to provide extra support for a claim which is the therapeutic good's indication or intended purpose. If advertisers do use citations in the advertisement, the requirements at Section 15 of the Code will apply.

'Data on file'

Sponsors sometimes want to use their own, unpublished scientific studies to support claims. If such a study is referenced in an advertisement, the term 'data on file' is not sufficient to meet the Code requirements for providing enough information to allow consumers to access the study.

Tips for producing a compliant scientific claim

Use clear terminology that can be readily understood by the average consumer.

Be wary of using statistical data including graphs and scientific jargon.

Only use supporting studies from reputable (e.g. peer reviewed) and verifiable sources.

Only reference studies that are relevant to the claim.

Ensure studies are referenced correctly in the advertising so that they are accessible.

Do not exaggerate or misrepresent the conclusions of a study.

Compliant scientific claims are just the first step to a compliant ad. Remember to ensure that your advertising complies with the other applicable requirements in the *Therapeutic Goods Act 1989* and the Code.



More information

Guidance on section 15 of the Advertising code:

www.tga.gov.au/book-page/part-2-general-requirements-advertising-therapeutic-goods#s15

Advertising Hub:

www.tga.gov.au/advertising-hub