Health therapies and evidence

Advertising Guidance (non-broadcast and broadcast)

Legal, decent, honest and truthful

CAP

Foreword

The Committee of Advertising Practice (CAP) offers guidance on the interpretation of the UK Code of Advertising (the CAP Code) in relation to non-broadcast marketing communications.

The Broadcast Committee of Advertising Practice (BCAP) offers guidance on the interpretation of the UK Code of Broadcast Advertising (the BCAP Code) in relation to broadcast marketing communications.

Advertising Guidance is intended to guide advertisers, agencies and media owners how to interpret the Codes but is not a substitute for those Codes. Advertising Guidance reflects CAP's and/or BCAP's intended effect of the Codes but neither constitutes new rules nor binds the ASA Councils in the event of a complaint about an advertisement that follows it.

For pre-publication advice on specific non-broadcast advertisements, consult the CAP Copy Advice team by telephone on 020 7492 2100, by fax on 020 7404 3404 or you can log a written enquiry via our online request form.

For advice on specific radio advertisements, consult the Radio Advertising Clearance Centre (RACC), and for TV advertisements, Clearcast.

For the full list of Advertising Guidance, please visit our website.

Background

This advice is intended to help marketers of health therapies comply with the CAP Code, particularly online, and to understand the role of evidence in the ASA's decision-making. It is also relevant to all types of marketing communications regulated by the ASA.

What are the key requirements of the Codes?

The Advertising Codes (the CAP Code for non-broadcast ads and the BCAP Code for TV and radio ads) have been developed to make sure that UK advertising is legal, decent, honest and truthful for the benefit of consumers, business and society. The ASA views ads including advertising claims from the perspective of the audience, typically consumers, and requires advertisers to substantiate claims with appropriate evidence.

The likely effect of a marketing communication is generally considered from the point of view of the average consumer whom it reaches or to whom it is addressed. The average consumer is assumed to be reasonably well-informed, observant and circumspect.

In some circumstances, a marketing communication may be considered from the point of view of the average member of a specific group:

- If it is directed to a particular audience group, the marketing communication will be considered from the point of view of the average member of that group.
- If it is likely to affect the economic behaviour only of a clearly identifiable group of people who are especially vulnerable in a way that the advertiser could reasonably foresee, because of mental or physical infirmity, age or credulity, the marketing communication will be considered from the point of view of the average member of the affected group.

Members of the public that have or believe they have a health condition for which medical supervision should be sought are potentially vulnerable to misleading claims that a product or service will help that condition.

More information about the UK Advertising Codes and the ASA can be found here: www.cap.org.uk / www.asa.org.uk .

Do the Codes and ASA regulation relate to all aspects of my business?

The Codes cover your advertising, including online marketing communications. Any private correspondence or conversations that you have with clients or potential clients are not covered by the Codes. We do not regulate your business practices in general.

Are there differences between how you assess different media?

All advertising will be assessed under the relevant Code (for TV and radio, the BCAP Code and for non-broadcast media, the CAP Code) and the overall context will be taken into account. However the rules relating to evidence, testimonials and misleading or harmful advertising are broadly the same across all media.

However, the Codes do recognise that the choice of media often influences how readers will interpret claims and what might be acceptable in one medium might not be acceptable in another. For example, websites offer greater scope for explanation and background information. In short, each advertisement is assessed on a case-by-case basis.

I don't claim to 'cure', why can't I claim to 'treat' certain conditions?

Whether you use the words 'treatment', 'treat' or 'cure', all are likely to be seen by members of the public as claims to alleviate effectively a condition or symptom. We would advise that they are not used either directly or indirectly, through the use of visuals for example. Of course, if evidence has been shown to support the claims, then these words can legitimately be used.

Marketers should be mindful that merely listing medical conditions could imply their treatment or therapy is effective.

What standards are applied to evidence?

The position taken by the ASA is a tried and tested one which has developed over the course of many years. It reflects the opinion of the wider scientific and academic community, rather than judgements made solely by the ASA.

There are many aspects that are taken into consideration when evidence is reviewed and each claim is judged on its merits alongside the evidence presented to support it.

Evidence submitted for health claims should normally include at least one adequately controlled experimental human study (12.1 Objective claims must be backed by evidence, if relevant consisting of trials conducted on people. If relevant, the rules in this section apply to claims for products for animals. Substantiation will be assessed on the basis of the available scientific knowledge.) but an adequately controlled observational human study might be sufficient in some circumstances.

If the body of evidence does not include at least one adequately controlled experimental human study, the ASA will usually need to be convinced that the data supplied is sufficiently compelling. A convincing rationale would need to be provided as to why commissioning an experimental human study would be impractical.

'Before and after' studies with little or no control, studies without human subjects, self-assessment studies and anecdotal evidence are unlikely to be considered acceptable as sole support for a "new" (For example, an unproven claim that has not been made before in advertising.) claim relating to physiological or psychological action or function in humans.

On their own, outcome studies or audits may not be sufficient as a rigorous basis for claims as there is little way of controlling for bias or for other influences that may have a bearing on the results. In addition, the claims should be able to be applied across the population – the evidence should therefore reflect the targeted consumer base, whether general or specific.

More information is given in the CAP Help Note on Substantiation for health, beauty and slimming claims.

My therapy has been used for hundreds / thousands of years. Is that sufficient to make claims for its efficacy?

We appreciate that many therapies have historical origins and traditionally held beliefs. However, this is not a robust basis on which to make health claims.

You can describe the history and tradition of a therapy, but in doing so you must be careful not to stray into making efficacy claims, whether direct or implied, if you do not hold evidence to make those claims.

I work in a holistic field. Why does the ASA require evidence on a rigid scientific model? This model does not address all aspects of my approach or outcomes?

Our position on the acceptability and appropriateness of evidence is in line with the weight of scientific and academic opinion. We encourage professional organisations in the health therapies sector to engage with the wider scientific and academic community to develop new and rigorous methodologies that take account of the holistic nature of their therapies.

Nevertheless, any new trial methodology should still have a robust basis and outcomes to ensure that the consumer can make informed decisions based on the claims made in marketing communications, which will be assessed on the basis of available scientific knowledge. We aim to ensure that our approach towards evidence and methodology is consistent across all sectors, including those outside the health sector.

Has the ASA assessed all the evidence?

It is the advertiser's responsibility to hold evidence for the claims they make, and it is stipulated in the Advertising Codes that evidence must be held by the advertiser prior to making the claim.

Advertisers must submit documentary evidence to the ASA to support any claims they make; the ASA will not seek out the evidence to establish the veracity of the claim for you.

When submitting evidence for "new" or "breakthrough" claims, sound data, relevant to the advertised claim(s), should be collated to form a body of evidence. The totality of this evidence is important; marketers should not ignore sound data that does not support the "new" claim, especially where current opinion is divided.

Where evidence is limited to very few studies, the studies should have robust results to ensure the basis for the claim is sound.

Why can't I refer to the many positive studies and ongoing research?

The CAP Code is clear in that "... Substantiation will be assessed on the basis of the available scientific knowledge..." (rule 12.1) and goes on to state ".... Accurate and responsible general information about conditions [for which medical supervision should be sought] may, however, be offered." (rule 12.2).

Citing only positive research is unlikely to provide an accurate or responsible reflection of the available information. Marketers should therefore ensure that the presentation of the research reflects the balance of data and if informed opinion is divided, the data (and any related claims) should not be portrayed as universally agreed.

Where the evidence is finely balanced, it might be acceptable to preface claims with "some experts believe…" or similar.

The online environment has greater scope for providing information in a discursive or detailed way. Providing links to information such as published research is likely to fall outside the remit of the ASA if they are presented in a section of the website that is not directly connected with the sale or supply of your products or services. For example, under a separate tab labelled 'research' or 'further reading'.

Do you accept feedback that I have had from my clients as evidence?

We understand that there are various ways to conduct a trial and that many therapies take into account more than just clinical outcomes. Nevertheless, patient feedback alone is very unlikely to substantiate objective claims about the effectiveness of a therapy or product. If you do use customer feedback, it should form part of an appropriate trial methodology. This approach ensures that the evidence is appropriately balanced and independently verifiable in order to ensure that any potential bias is ruled out and an appropriate trial methodology has been followed.

Are recommendations from NICE or similar organisations acceptable?

We will consider robust evidence from authoritative sources, for example NICE, the Cochrane Collaboration or a thorough, independent review from an impartial body e.g. the Health Select Committee.

However, in assessing that evidence we will consider how applicable it is to support a claim in the context of an advertisement directly targeted at consumers or a specific group of consumers, some of whom may be vulnerable.

This is because it is often the case that NICE and similar organisations make their recommendations relevant to a clinical setting e.g. the NHS. So, in those settings, decisions about treatment and care are likely to be made by a suitably qualified healthcare professional. We on the other hand consider advertising claims where consumers will be making decisions about whether to use a therapy in a setting that is independent of a clinical decision or environment. Our role is to ensure that advertising is legal, decent, honest and truthful in order that consumers are not misled or harmed by efficacy claims where they may not have the benefit of advice from an appropriately qualified medical professional.

Can I use trials that have been conducted on a non-UK population to substantiate my claims?

It has long been the ASA's position that evidence should be applicable to the advertised audience and each trial is reviewed on a case-by-case basis subject to our usual procedures. In theory, a trial conducted in the US, for example, may be acceptable if it is demonstrably applicable to the population targeted by the advertising. However, if a trial does not represent the targeted population then it may be deemed unsuitable to substantiate claims. For example, a therapy for back pain, conducted on the elderly may not be a suitable basis to advertise to the general public.

Similarly, a trial for a diet product conducted on a group of people who have very different dietary habits in general, may not be applicable to or replicable in a UK population.

Is it possible to have my evidence assessed?

In the first instance, we advise that you contact your professional or trade organisation as we have worked with many of them to develop guidelines about specific therapies and advertised claims that would comply with the CAP Code.

If you have new, published evidence then we would ordinarily be happy to assess it subject to the scope of the request and available resources. However, we advise that the evidence presented is read alongside and reflects our Help Note on Substantiation for health, beauty and slimming claims to ensure that we can utilise our time and resources wisely.

Can I use testimonials in my advertising?

Under the CAP Code, testimonials can be used, but with care. The ASA has a long-standing rule that if a testimonial includes a direct or indirect claim to relieve a condition or symptom then this will be subject to the same rules as any other claim. So where efficacy has not been proven, they should not be used to imply that it is.

A similar rule applies in all sectors – advertisers cannot use testimonials to make claims that would otherwise not be permitted under the Advertising Codes.

Why do you allow consumer-based claims for some products and not for health therapies such as mine?

The type of claim will determine the type of evidence or methodology needed to support it.

Claims for a consumer product are often very different, both in content and context to those made by a health therapist. So a sensorial or subjective claim such as ‘my skin feels smoother’, ‘I felt invigorated’ or ‘I was more relaxed after my therapy session’ might require only consumer opinion research to back it up. Likewise, a claim to be a bestseller will be seen by us and consumers (some of whom may be particularly vulnerable) as different to a claim that therapists can alleviate a particular symptom or medical condition.

A health-related efficacy claim for a treatment requires a higher level of evidence because it deals with consumers’ health where the potential risk from misinformation could be great. We apply the same standard across the board, including for GMC registered doctors.

In addition, if a consumer product claims to cure a disease or alleviate a symptom, similar standards of evidence would be applied. And if it's a medicine, it would need to have a licence.

What are the criteria for selecting an expert to review evidence?

In all circumstances, the evidence is evaluated initially to assess whether it supports the claims made in the advertisement.

If the evidence appears to be of a sufficiently high quality and if we have insufficient expertise to assess it fully, we may pass the evidence on to an expert for their assessment.

Experts are selected on the relevance of their knowledge and experience. We ensure they have appropriate and relevant qualifications to judge the materials. Some have medical qualifications, whilst others work in academic settings in universities and / or the NHS. We choose experts who are demonstrably impartial and unprejudiced by financial considerations.

It is important to note that the experts assess the evidence and not the marketing material.

My trade / professional association has given me advice that differs from yours. What should I do?

Ultimately, it is your responsibility, both under the Codes and under the law, to ensure that your advertising does not mislead. No organisation can absolve you of this fact.

The Copy Advice team is committed to helping you comply with the relevant sections of the Code, which goes a long way to ensuring compliance with the law. Where we have not seen evidence to prove a claim to treat or alleviate a condition, for example, or the evidence is unlikely to meet the standards of the wider scientific and academic community, we will advise you to remove or amend your claim.

In the event of receiving a complaint about your ad, the ASA would consider the complaint against the Code. Therefore, advertising - regardless of any other guidance you receive from other bodies - should comply with the UK Advertising Codes.

The advice in this document is based on the current position of the ASA and CAP. All formally investigated cases are published on the ASA's website, www.asa.org.uk.

You may also find it useful to keep up-to-date with news from the MHRA regarding homeopathy (www.mhra.gov.uk).

Committee of Advertising Practice
Mid City Place, 71 High Holborn
London WC1V 6QT
Telephone 020 7492 2200
Textphone 020 7242 8159
Email: enquiries@cap.org.uk
@CAP_UK

Legal, decent, honest and truthful

CAP