Health, beauty and slimming claims substantiation

Advertising Guidance (non-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.

CAP Help Notes offer guidance for non-broadcast marketing communications under the UK Code of Non-broadcast Advertising, Sales Promotions and Direct Marketing (the CAP Code). For advice on the rules for TV or radio commercials, contact Clearcast www.clearcast.co.uk for TV ads or the RACC www.racc.co.uk for radio ads.

Background

These guidelines, drawn up by the Copy Advice team, are intended to help marketers, agencies and media interpret the rules in the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing as far as they relate to the subject discussed. They are based on past ASA cases and neither constitute new rules nor bind the ASA Council in the event of a complaint about a marketing communication that follows them.

The Code states:

3.7 "…marketers must hold documentary evidence to prove claims that consumers are likely to regard as objective and that are capable of objective substantiation. The ASA may regard claims as misleading in the absence of adequate substantiation". Note that the ASA will take into account the impression created by marketing communications as well as specific claims. It will adjudicate on the basis of the likely effect on consumers, not the marketer's intentions.

3.13 "Marketing communications must not suggest that their claims are universally accepted if a significant division of informed or scientific opinion exists.".

Three types of health, beauty and slimming claims are made for products (or services): sensory or impressionistic subjective claims; uncontroversial or established objective claims; and "new" objective claims.

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.

Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA or EMEA, or for a CE-marked medical device. A medicinal claim is a claim that a product or its constituent(s) can be used with a view to making a medical diagnosis or can treat or prevent disease, including an injury, ailment or adverse condition, whether of body or mind, in human beings.

Secondary medicinal claims made for cosmetic products as defined in the appropriate European legislation must be backed by evidence. These are limited to any preventative action of the product and may not include claims to treat disease.";

13.1 "Any claims made for the effectiveness or action of a weight reduction method or product must be backed, if applicable, by rigorous trials on people…";

Sensory/impressionistic subjective claims

Claims that cannot be proved objectively, such as "no other shower gel leaves you feeling fresher", might be understood to be opinion or might only require satisfactory consumer research to back them up.

Uncontroversial/established objective claims

These might constitute satisfactory proof for uncontroversial/established claims:

- A clear and concise account of the physiological effect of a product on the intended subjects, perhaps supported by an expert opinion (provided this reflects general scientific opinion, i.e. is accepted, or likely to be accepted, by most relevant experts);
- Information contained in authoritative reports, reputable guidelines or other published material that represents or reflects general scientific opinion. For example, in relation to beauty claims, reports published by the Journal of the Society of Cosmetic Chemists, the British Journal of Dermatology and the Journal of Investigative Dermatology.

"New" objective claims

For "new" or "breakthrough" claims, sound data, relevant to the claim made, 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. There are now generally recognised ways of collating existing data (where it is not immediately available) by conducting a systematic review of all available scientific evidence and evaluating it for its relevance (e.g. by using standardised data extraction procedures and electronic databases).

Evidence for health and slimming claims (excluding food and food supplements)

A body of evidence might consist of one or more of these categories:

- experimental human studies in which an “intervention” group (or groups) of human subjects uses the product under examination and a “control” group uses a control, with neither subjects (single-blind) nor researchers taking the measurements (double-blind) knowing which subjects are in which group (sometimes referred to as clinical studies or placebo-controlled trials);
- observational human studies in which a group or groups of people are studied in their environment (sometimes called epidemiological studies);
- an appropriate expert’s extrapolation of relevant findings from seemingly irrelevant human studies (e.g. where a product’s proven effect on ill people provides the basis of proving the proposed effect on those healthy people that the marketers wish to target);
- studies without human subjects (e.g. biochemical, cellular or animal studies);
- before and after studies with little or no control;
- self-assessment studies (to support objective statements that can be ascertained only by consumer observation);
- published and unpublished literature (perhaps supporting the rationale behind a claim);
- anecdotal evidence such as testimonials and endorsements.

Evidence for beauty claims

A body of evidence might consist of one or more of these categories:

- experimental human studies;
- within-subject comparisons of treated and untreated sites;
- studies without human subjects;
- before and after studies with little or no control;
- self-assessment studies;
- published and unpublished literature;
- anecdotal evidence.

Quality of data

The body of evidence should normally include at least one adequately controlled experimental human study but an adequately controlled observational human study might be sufficient in some circumstances. To consider acceptable a body of evidence that does not include at least one adequately controlled experimental human study, the ASA's or CAP's experts will usually need to be convinced of the soundness of the data provided and the futility or impracticality of commissioning an experimental human study. Before and after studies with little or no control, studies without human subjects, self-assessment studies, published and unpublished literature and anecdotal evidence are unlikely to be considered acceptable as sole support for a "new" claim relating to physiological action in humans (though in vitro studies may provide sole support for inherent activity, e.g. anti-oxidant action).

Sound individual studies should:

- follow a recognised methodology that controls both for the "placebo" effect and for other factors unconnected with the proposed action of the product (e.g. effects brought about by the way in which a medical device is used or a cream is applied). The most reliable method of allocating subjects to different groups in experimental human studies is by random allocation ("randomised" studies). Reliability can also normally be gained by incorporating a "cross-over" element (the subjects in the two groups swap with each other after a sufficient period in their respective groups and with a sufficient period of "rest" in between). Similarly, some designs for observational human studies are more reliable than others; for example, studies that are planned in advance and undertaken prospectively are less likely to be biased than studies carried out retrospectively. The validity of data, however, depends not only on the protocol of the study but also on how well the study was designed, carried out and analysed;
- be large enough to demonstrate the proposed effect. A desirable size for a study can be assessed using standard statistical formulae (though meta-analysis, the pooling of results from several studies, might allow valid conclusions to be drawn from two or more small studies);
- normally be carried out on a representative cross-section of a population similar to that of the UK or on a representative sample of the sector of the population at which the product is targeted;
- involve the intervention group consuming, applying or using a reasonable and, as far as possible, quantified amount of the product at a reasonable frequency (this should reflect the normal usage proposed for the product);

- where appropriate, be of sufficient duration to ensure that any beneficial effect is maintained over a reasonable period of time and is not a short-term response to which the body or mind adjusts. A follow up period might also be needed depending on the nature of the effect studied;
- where appropriate, take into account confounding factors (e.g. smoking) and other relevant variables;
- produce statistically, and physiologically, significant results by tests selected before the studies began;

Credibility of data

If studies have not been published in reputable, peer-reviewed journals (and indeed studies often have not), an objective review should be carried out by a suitably qualified individual possessing relevant expertise before the data is submitted to the ASA or CAP.

Submitting data

Where possible, the body of evidence should be provided in a clearly set out indexed dossier.

This might include:

- the “new” or “breakthrough” claims to be supported;
- the composition of the product and an explanation of how it works;
- precise details of who might benefit and why;
- the quantity of product consumed, applied or used and its frequency of use;
- the preferred experimental human studies (ideally, with greater emphasis given to those that have been published or subjected to assessment by a suitably qualified expert). If several studies are provided to back up several claims, it should be clear which study supports which claim;
- data supporting the experimental human studies (e.g. observational, cellular, animal and self-assessment studies);
- anecdotal evidence.

Matters of opinion

Marketers who do not hold satisfactory evidence of the purported qualities of their product can ask the CAP Copy Advice team for help in devising an acceptable marketing platform. This might involve the marketers giving their opinion on the desirability of their product, though they must clearly be expressing their opinion and not stating fact. Claims that go beyond subjective opinions are subject to the Code’ rules on substantiation.

Division of opinion

If informed opinion about the acceptability of a “new” claim is divided, the claim should not be portrayed as universally agreed. Such a claim might be acceptable if prefixed by “some experts believe…”, or similar. To confirm that a division of informed opinion exists, documentary evidence, perhaps in the form of published articles, conference minutes, studies or published correspondence, should be provided. This should show that the acceptability of the “new” claim is under debate, with a reasonable number of suitably qualified, competent experts believing it to have been adequately supported.

Guidance

Information about recognised methodology for studies to support health and slimming claims can be sought from those medical journals that review papers for publication. Marketers wishing to support beauty claims may wish to consult the European Cosmetic, Toiletry and Perfumery Association (COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products. Please note that the COLIPA Guidelines endorse the use of some tests, most notably the consumer self-assessment test, that are unlikely to be considered by the ASA’s or CAP’s experts as satisfactory sole supporting data for proving “new” claims.

Advice on specific marketing communications is available from the Copy Advice team by telephone on 020 7492 2100, by fax on 020 7404 3404, or you can log a specific written enquiry via our online request form http://www.cap.org.uk/Bespoke. The CAP website at www.cap.org.uk/advice contains a full list of Help Notes as well as access to the AdviceOnline database, which has links through to relevant Code rules and ASA adjudications.

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