

Claims about health in ads for e-cigarettes

CAP and BCAP's regulatory statement



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1. Executive Summary

Following consultation, CAP and BCAP are amending rules in each of their Codes to remove the absolute prohibitions on claims being made about health in lawful advertisements for electronic cigarettes. Since this prohibition came into force in 2014, the evidence for the relative safety of e-cigarettes has improved, alongside a regulatory regime to set product standards. In light of these sector-wide changes, CAP and BCAP consider that an absolute prohibition on health claims in lawful ads for e-cigarettes can no longer be justified. Marketers will still need to hold evidence for any claims in their ads, and the requirement to carry MHRA authorisation for medicinal claims is unchanged.

Nicotine-containing e-cigarettes are legally banned from advertising in a range of media, including magazines, TV, and radio.¹ The changes made to the Codes do not undo or otherwise affect the application of these media bans.

In 2014, CAP and BCAP introduced sector-specific advertising rules controlling the content, placement, and scheduling of e-cigarette advertisements to answer concerns from the public and industry as to how they could be advertised.

In May 2016, the European Tobacco Products Directive 2014/40/EU (the TPD) came into effect in all EU member states and brought in a range of advertising prohibitions for unlicensed, nicotine-containing products. The prohibitions on broadcast advertising were transposed directly into the BCAP Code. The prohibitions on non-broadcast advertising were transposed into Part 7 of The Tobacco and Related Products Regulations 2016 (the TRPR) which, after consultation, CAP approximated in its own Code in February 2017.

These rules included a prohibition on health claims (any claim that a relationship exists between an e-cigarette or one of its constituents and health). This prevented a range of claims, including claims that e-cigarettes are healthier or safer than smoking tobacco. The prohibition on health claims was introduced at the end of 2014 to respond to an identifiable potential for harm: specifically, that there was strong evidence of a wide variation in quality, safety and efficacy of products on the market that was of significant concern to the MHRA and other major stakeholders at that time. The industry itself has started to develop product standards, including the publication, in 2015, of a Publicly Available Specification (PAS). TRPR has introduced a range of safety, efficacy and reporting requirements which the industry is now implementing.

These changes caused CAP and BCAP to question whether they could continue to justify an absolute prohibition on health claims. They therefore invited respondents to their 2016 consultation to submit views and evidence on whether the Codes might allow for substantiated health claims to be made for unlicensed e-cigarettes. Having carefully evaluated the responses, CAP and BCAP considered that the evidence no longer supported an outright prohibition on health claims for e-cigarettes. They therefore proposed changing their rules to remove this prohibition.

CAP proposed amending rule 22.5 as follows:

¹ <https://www.asa.org.uk/resource/electronic-cigarette-advertising-prohibition.html>

<p>Existing text</p> <p>Removed text</p>	<p>22.5 Marketing communications must not contain health or medicinal claims unless the product is authorised for those purposes by the MHRA. E-cigarettes may be presented as an alternative to tobacco but marketers must do nothing to undermine the message that quitting tobacco use is the best option for health.</p>
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BCAP proposed amending rule 33.5 as follows:

<p>Existing text</p> <p>Removed text</p>	<p>33.5 Advertisements must not contain health or medicinal claims unless the product is authorised for those purposes by the MHRA. E-cigarettes may be presented as an alternative to tobacco but marketers must do nothing to undermine the message that quitting tobacco use is the best option for health.</p>
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Having evaluated the responses to the consultation, CAP and BCAP have decided to make this change, which will mean that marketers will no longer be prohibited from making claims about the relationship between their products and health. However, this will not automatically permit any particular claim; as in other sectors, e-cigarettes advertisers will have to hold robust substantiation for any claims about health which they make.

BCAP has also approved two minor changes to its Code, which remove the requirement to state nicotine content and to make the e-cigarettes section permanent.

The changes take effect in both Codes immediately and will be subject to review after 12 months.

2. Policy background and the decision to consult

2.1 Policy background

In 2014, CAP and BCAP introduced sector-specific rules controlling the content, placement and scheduling of e-cigarette advertisements to answer concerns from the public and industry as to how they could be advertised.

In May 2016, the European [Tobacco Products Directive 2014/40/EU](#) (the TPD) came into effect in all EU member states and introduced a range of advertising prohibitions for unlicensed, nicotine-containing products. The prohibitions on broadcast advertising were transposed directly into the BCAP Code and the prohibitions on non-broadcast advertising were transposed by [Part 7 of The Tobacco and Related Products Regulations 2016](#) (the TRPR) which, after consultation, [CAP approximated in its own Code in February 2017](#).

The law has complex effects, prohibiting ads for some products, but not others, and only in certain media. CAP's rule ([22.12](#)) and the accompanying [Advertising Guidance](#) explain the nature of the prohibitions at length.² In brief, ads for nicotine-containing e-cigarettes and e-liquids which are not licensed as medicines (a definition which describes the overwhelming majority of products on the market) can only be advertised in the following media:

- outdoor advertising, including digital outdoor advertising;
- posters on public transport (not leaving the UK);
- cinema;
- direct hard copy mail;
- leaflets;
- private, bespoke correspondence between a marketer and a consumer;
- media which are targeted exclusively to the trade; and
- limited factual claims about products on marketers' own websites and other non-paid for online space under their control

Non-nicotine containing products that are designed so they cannot be refilled with nicotine can be advertised in all media but must not indirectly promote nicotine-containing products in media where nicotine-containing products cannot be advertised; for example by sharing a brand name.³ CAP and BCAP are not currently aware of any ads for, or the existence of, separately-branded, exclusively-non-nicotine containing products.

Where any e-cigarette is lawfully advertised, irrespective of whether or not it contains nicotine or whether or not it is licensed as a medicine, it must comply with all the general and product-specific rules that [CAP](#) and [BCAP](#) introduced in 2014.

² CAP's original [consultation document](#) (pp 4-5) and the Department of Health's [Guidance](#) on their transposition of the TPD provide more background on the legal basis of these prohibitions.

³ CAP and BCAP's [Advertising Guidance](#) includes advice for marketers on how to avoid indirect promotion of nicotine products.

2.2 CAP and BCAP's decision to consult

The rules introduced in 2014, which continue to apply to lawful advertisements, prohibit advertisements for e-cigarettes from making claims about the effect of products on people's health. CAP and BCAP created this prohibition because there was no specific regulatory framework for e-cigarettes as a product category and there were significant concerns about the variability in quality and safety about products on the market.

In 2016, CAP and BCAP sought stakeholders' views on whether that prohibition was still proportionate given advances in product regulation, quality, and safety. The majority of respondents suggested that it was not. In 2017, CAP and BCAP therefore [consulted](#) on a proposal to remove the prohibition from both of their Codes by amending the relevant Code rules.

Following the consultation, BCAP considered that the consultation might have given rise to confusion among some readers, by proposing the removal of the prohibition on health claims from unlicensed nicotine-containing e-cigarettes only. Unlicensed, nicotine-containing e-cigarettes cannot be advertised in broadcast media; BCAP noted therefore that the proposal to remove the ban on health claims for e-cigarette products might well be very limited in its application, but stated its wish to make the change nevertheless, in the interests of consistency with CAP's regime and in order to reflect the best available evidence. Because BCAP was not aware of any non-nicotine containing e-cigarette on the market, the consultation question dealt only with nicotine-containing e-cigarettes (which may not be advertised in broadcast media unless licensed).

A clarification note was therefore issued to rephrase the question to make clear that health claims in TV and radio advertisements for unlicensed non-nicotine containing e-cigarettes would not be prohibited, provided the advertisement complied with all other applicable rules. However, all TV and radio advertisements for nicotine-containing e-cigarettes would continue to be prohibited unless they were for licensed medicinal products, in which case a health claim could be made subject to the conditions of the licence. A period of time for comments was provided; the only feedback received was from British American Tobacco (a tobacco and e-cigarette company) confirming that its response to the question remained unchanged.

3. Decisions

3.1 Responses to the proposal

CAP and BCAP received a total of 49 responses from industry, public health, NGOs and private individuals. A full evaluation of responses is published alongside this document.

A majority of respondents supported the proposal, including ASH, Cancer Research, Public Health England and the Royal College of Physicians as well as those in the e-cigarette industry. The recurring key arguments in support are that:

- product quality has improved markedly since 2014 and since the implementation of product standards by TRPR;
- e-cigarettes are a less harmful alternative to smoked tobacco and have a significant role to play in smoking cessation; and
- public understanding of the relatively lower risk is limited and appears to be declining, and marketers are currently unable to correct this understanding through their own advertising.

CAP and BCAP note, however, that this support is not unqualified. Many of the respondents supporting the proposal pointed out that while e-cigarettes are less harmful than tobacco, they are not safe, and there is no evidence of a significant health benefit from using e-cigarettes alongside tobacco.

A smaller number of stakeholders opposed the proposal, including ASH Scotland, the British Medical Association, the Trading Standards Institute and the Faculty of Public Health. These respondents acknowledged that e-cigarettes are likely to be safer than smoking tobacco but expressed many of the same concerns as those who supported the proposal; for example that e-cigarettes are not harm-free and that there is an absence of long-term studies about their effects. Some of these respondents argued that medicines licensing offers a route for those wishing to make health claims.

3.2 CAP and BCAP's consideration

CAP and BCAP created the prohibition on health claims in 2014 because of concerns about product quality and safety at that time; it has no other legal or regulatory basis.⁴

In deciding whether to remove or retain this prohibition, CAP and BCAP have considered whether the evidence of harm remains so significant that all advertisers must be prohibited from making claims about people's health.

CAP and BCAP note that support for the removal of the prohibition is not universal amongst consultation respondents, and that even those who support it do so with qualification. However, CAP and BCAP considered that the responses to their consultation demonstrate

⁴ CAP and BCAP note that the TPD and TRPR prohibit claims on product packaging, but this prohibition does not extend to advertising.

the ways in which the public health debate and the regulatory environment have changed since 2014.

CAP and BCAP take seriously the concerns expressed by those who oppose the change. However, having carefully considered the consultation responses, particularly the arguments about the much-improved nature of products, the positive attitude taken to the comparative health benefits of these products by major public health stakeholders⁵, and the valid criticism that their regulation was preventing marketers communicating facts about relative risk, CAP and BCAP consider that they can no longer maintain the absolute prohibition on health claims and are removing it with immediate effect.

CAP will amend rule 22.5 of its Code as follows:

22.5 Marketing communications must not contain ~~health or~~ medicinal claims unless the product is authorised for those purposes by the MHRA. E-cigarettes may be presented as an alternative to tobacco but marketers must do nothing to undermine the message that quitting tobacco use is the best option for health.

BCAP will amend rule 33.5 of its Code as follows:

33.5 Advertisements must not contain ~~health or~~ medicinal claims unless the product is authorised for those purposes by the MHRA. E-cigarettes may be presented as an alternative to tobacco but marketers must do nothing to undermine the message that quitting tobacco use is the best option for health.

3.3 Medicinal claims

The prohibition on medicinal claims remains in place in the rule: this is a legal requirement and mirrors relevant rules in the Medicines section of both Codes. Medicinal claims include smoking cessation and reduction claims, such as those seen in ads for licensed nicotine replacement therapies (NRT) and a product would need authorisation from the MHRA before such claims could be made for it.

3.4 Application to broadcast advertising

The advertising prohibitions in the TPD (reflected in the BCAP Code) have now eliminated advertisements for unlicensed, nicotine-containing e-cigarettes in TV and radio. Only a non-nicotine containing product / brand which does not indirectly promote a nicotine-containing product / brand (for example by sharing a brand name) can be advertised and make a health claim. BCAP is not aware of such a product having been marketed in broadcast media but considers that it is possible.

⁵ For example, Public Health England referred to their recent review of the research on the relative safety of e-cigarettes: <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>. ASH and RCP both referred to a recent RCP report on harm reduction through e-cigarettes: <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

3.5 Twelve-month review

CAP and BCAP will review the effect of this change to their rules in 12 months to ensure that it functions as intended.

4. Consequence of the change and advice to marketers

4.1 General points

Following the change, advertisers of e-cigarettes are no longer prohibited from making claims about the link between their products and health. However, CAP and BCAP are not pre-approving any particular claim or type of claim; marketers must hold evidence to substantiate any claims they make. The ASA will examine any complaints about health claims on a case-by-case basis.

Many respondents to CAP and BCAP's consultation expressed views based on the available general evidence and what this may mean for the types of claims that might be acceptable in ads. CAP and BCAP have summarised some of these concerns below with some general guidance; however, this advice is not binding on them or the ASA Council, who may take a different view.

When making health claims for e-cigarettes marketers must:

- ensure that those claims are not misleading; and
- hold robust evidence to substantiate them, in line with CAP's [Advertising Guidance on Substantiation for Health Claims](#).

Evidence must be provided to the ASA if requested and must be **specific to the advertised product/s**. Where a claim is made for a brand or range, it should be based on evidence for the entire brand or range.

Reports which describe the general benefits of using e-cigarettes rather than smoking tobacco, even when those reports are authored by a credible body, are unlikely to be considered adequate substantiation for a claim about a specific product.

4.2 Expert views expressed in consultation

The consensus amongst public health experts is that:

- e-cigarettes are less harmful than smoked tobacco, but they are not "safe";
- the evidence does not support any positive health benefits from vaping other than as an alternative to tobacco; and
- there is no evidence of a significant health benefit from using e-cigarettes alongside tobacco.

For these reasons, CAP and BCAP consider that the following types of claims are unlikely to be capable of substantiation and marketers should consider avoiding them:

- claims of absolute safety;
- claims of positive health benefits; and
- claims that explicitly encourage use of e-cigarettes alongside tobacco ('dual use').

4.3 References to the opinions of third parties

CAP and BCAP are aware that many public health bodies, including Public Health England and the Royal College of Physicians, have made favourable statements about the potential health benefits e-cigarettes, which marketers may wish to repeat or reference in their ads. There are a number of well-established principles of ASA enforcement and CAP advice in relation to testimonials and endorsements which marketers should note:

- Where an ad cites or repeats a claim made by another source, the ASA is highly likely to regard that claim as being an implied claim for the advertised product/s. For example, where an ad for an e-cigarette references a public health report that states “e-cigarettes are safer than tobacco”, the ASA will almost certainly expect the marketer to demonstrate that claim can be substantiated for the advertised product.
- Reports may not relate to the advertised product or may have other limitations which mean that the ASA may not agree with their conclusions.

4.4 Smoking cessation and reduction claims

For the reasons set out in section 3.3, marketers of e-cigarette products and brands must avoid making claims that their products can help in cutting down or quitting tobacco smoking unless the product has a medicines licence indicating its suitability for that purpose. It may be acceptable for generalised public health messaging to make smoking cessation and reduction claims for e-cigarettes generally, provided that it does not promote a particular product or brand. Advertisers should seek guidance from CAP’s Copy Advice team for non-broadcast ads, or the relevant body in broadcast media.

5. Non-broadcast public health messaging which refers to e-cigarettes

Prior to the launch of their last consultation, CAP and BCAP became aware that some public health bodies wished to place advertisements promoting e-cigarettes as a healthier alternative to tobacco. The Department of Health in England has announced its intention to “include within quit smoking campaigns messages about the relative safety of e-cigarettes”.⁶

CAP understands that such campaigns are lawful in all non-broadcast media⁷, including those in which products and brands themselves cannot be advertised because of the prohibitions in the TRPR (now reflected in the CAP Code).

However, wherever such advertisements are placed they must comply with the CAP Code, including those rules which control the content and placement of ads for, or which refer to, e-cigarettes.

In its consultation, CAP invited respondents to consider whether there might be circumstances in which CAP or the ASA might retain the discretion not to apply these specific content and placement rules to public health campaigns which refer to e-cigarettes.

5.1 Nature of responses

In the consultation, CAP asked specifically whether the content rules which govern e-cigarette ads should always apply to public health messages which refer to e-cigarettes but which do not refer to a particular product or brand.

However, most respondents focused on the question of whether public health campaigns should be permitted at all. Although this was not the specific question, CAP notes the significant concerns expressed by many respondents about the circumstances in which public health campaigns might be placed by a commercial entity, including tobacco companies.

Importantly, CAP did not receive, in response to this question, any significant responses that set out what type of responsible public health message would be prevented by the current rules.

For these reasons, CAP is not making any changes to its rules as they apply to public health campaigns.

⁶ [Towards a Smokefree Generation: A Tobacco Control Plan for England](#); Department of Health and Social Care (England), July 2017, p.16

⁷ Guidance:Article 20(5), Tobacco Products Directive: restrictions on advertising electronic cigarettes: Department for Health and Social Care (England), 20 May 2016, see ‘Who the requirements apply to’.

6. Other administrative changes to the BCAP Code

In a previous consultation in 2016, BCAP consulted on, and subsequently decided on, two other administrative changes which it considered that it needed to make to its Code. After completing its governance processes with Ofcom, BCAP is now in a position to make those changes, which it will make alongside those set out above in relation to health claims. The two administrative changes are set out in the rest of this section.

6.1 Removal of rule 33.7

The first change is to remove rule 33.7 which requires ads to disclose whether products contain nicotine. BCAP proposed to remove this rule because nicotine-containing products can no longer be advertised in broadcast media unless medically licensed (in which case the requirement to state the ingredient is determined by the licence). BCAP received no significant objections to this proposal and is now making that change, retaining the rule number but deleting its content.

6.2 Retaining the Electronic cigarettes section of the BCAP Code

BCAP and Ofcom introduced the E-cigarettes section of the BCAP Code on an interim basis until the effects of the TPD could be examined further. In 2016, BCAP (and CAP) invited comments on the ongoing suitability of their rules to regulate lawful advertisements. While they received various comments in response to this question, they did not receive any significant arguments that the rules were unsuitable.

BCAP is therefore retaining the E-cigarettes section of its Code permanently, by way of the following amendment to the introduction to the section:

<p>Existing text</p> <p>Removed text</p>	<p>The Tobacco Products Directive</p> <p>Directive 2014/40/EU (on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC) came into effect in the UK on 20 May 2016. It prohibits advertisements on TV and radio which have the direct or indirect effect of promoting nicotine-containing e-cigarettes and e-liquids. The prohibition is set out in Section 10 (Prohibited Categories) and includes the full legal definitions of the products for which advertising is prohibited.</p> <p>E-cigarette products which are not caught by those definitions may continue to be advertised subject to the rules in this section on an interim basis, until such time as BCAP has reviewed their compatibility with the new rules. These are (i) Products which are licensed as medicines or medical devices, (ii) non-nicotine-containing liquids and refill containers, (iii) non-nicotine-containing disposable e-cigarettes and (iv) rechargeable e-cigarettes which are designed to be fitted only with cartridges containing non-nicotine-containing e-liquid. Advertisements for medicines / medical devices must also comply with the rules in Section 11 (Medicines, medical devices, treatments and health).</p> <p>Therefore, for the purposes of this section only, “electronic cigarette” means a product that can be used for the consumption of vapour via a mouth piece, or any component of that product, including a cartridge, a tank, an e-liquid and the device without cartridge or tank (regardless of</p>
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whether it is disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges), that is not prohibited from being advertised by Section 10.

The e-cigarette market continues to innovate rapidly and new products may emerge which may not be caught precisely by the above definition. The ASA may apply these rules in circumstances where it considers that an advertised product is sufficiently similar to warrant the protection provided by this section.

Depending on the formulation of their product and the means by which it is supplied, advertisers may have obligations relating to their advertising under chemical classification, labelling and packaging legislation. Broadcasters are advised to take legal advice to ensure compliance with the relevant law.

The changes in this document take effect immediately.

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