BCAP Medicines Consultation: Regulatory Statement

Proposals for amendments to the *Medicines, medical devices, treatments and health* section of the BCAP Code

Legal, decent, honest and truthful

Contents

The UK Advertising Codes are the responsibility of two industry Committees – the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) and are independently administered by the Advertising Standards Authority (ASA).

The Codes require advertisements across media to be legal, decent, honest and truthful, promoting consumer trust in advertising and maintaining fair competition between businesses. The Codes also include additional, sector-specific rules, such as those for alcohol, food and gambling, to ensure responsible advertising and the protection of vulnerable groups in certain sectors.

1. Summary

1.1 Changes to the Medicines section of the Code

The Broadcast Committee of Advertising Practice (BCAP), author of the UK Code of Broadcast Advertising (the BCAP Code), has decided to make changes to the *Medicines, medical devices, treatments and health* section ('Section 11') of the BCAP Code following a process of public consultation.

In 2013, BCAP issued a consultation on three separate policy issues that had arisen since the last comprehensive review of the Code in 2009. Following the evaluation of the consultation responses, BCAP has decided to:

- Amend the rule prohibiting advertisements for services offering remote treatment (11.13.1) to allow adequately regulated services to advertise on TV and radio;
- Amend the rule on smoking deterrents (11.18.2) to ensure that it does not conflict with medicines licencing provisions that now allow certain products to advertise using harm reduction claims; and
- Make several minor technical updates to the Code; primarily, in response to the enactment of the Human Medicines Regulations 2012 (HMRs).

This regulatory statement includes:

- Background to the issues and BCAP's reasons for consulting
- A summary of consultation responses
- BCAP's evaluation of responses
- Confirmation of BCAP's decision

Full evaluation tables of significant responses to each of the consultation questions are in Annex C. The tables include details of all significant points made by respondents and BCAP's response.

For further background and full details of the proposals, including BCAP's policy considerations, please refer to BCAP's consultation document.

2. Background

2.1 Policy objectives

BCAP's overriding objective is to prevent the inclusion of advertising in broadcast media, which may be misleading, harmful or offensive.

In this regard, it is particularly important that changes to Section 11 are given detailed consideration owing to the potential for irresponsible medicines-related and health-related advertising to cause harm to viewers and listeners. BCAP is also mindful of its specific responsibilities under its co-regulatory partnership with Ofcom, which derive from HMRs; in particular, the requirement for the ASA to consider certain types of complaint about medicines advertising.

At the same time, it is important to ensure that the Code is kept up to date and reflects developments in the underlying statutory frameworks upon which its rules are based.

2.2 BCAP's decision to consult

BCAP assessed the three policy issues and decided to consult on the following grounds:

- **Services offering to prescribe or treat remotely** – The Code currently prohibits services offering to prescribe or treat remotely from advertising on TV and radio. This provision dates from legacy versions of the Code that sought to protect viewers and listeners from services that were considered unlikely to meet basic regulatory standards. The growth of mainstream, more tightly regulated services using internet platforms, such as online pharmacies, has called into question the need for an absolute prohibition. In 2009, BCAP considered a proposal to relax the rule. However, on the advice of the regulators then responsible for UK pharmacy and healthcare service regulation, the proposal was not taken forward. Changes to the underlying regulatory framework were then on-going and it was felt that the new arrangements needed time to bed in. Having postponed its final consideration of the matter for two years, on the pre-consultation advice of key regulatory stakeholders, BCAP more recently decided to put a proposed relaxation to consultation.

- **Smoking deterrents and harm reduction** – In 2010, the MHRA announced the potential for it to license nicotine replacement therapy (NRT) products on a harm reduction platform. On public health grounds, they accepted that such products could reduce harm to smokers, by reducing consumption, moving away from the previous approach that regarded any level of smoking to be undesirable. BCAP decided to consult on an amendment to its rule on smoking cessation products and therapies, which prohibits claims that smoking is "safer" while the habit is being reduced, because of the potential for this rule to conflict with the new license indication that will allow authorised products to make harm reduction claims.

- **Technical updates reflecting legislation –** The HMRs came into force in August 2012 and were the culmination of the Medicines and Healthcare products Regulatory Agency's (MHRA) consolidation and review of UK medicines legislation. Following the 1968 Medicines Act there had been over 70 amending pieces of legislation, the more recent implementing successive EU Directives. The HMRs replaced virtually all of those pieces of legislation, including the principle instruments governing medicines advertising prior to August 2012; the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994.The HMRs consolidate the existing regime for regulating medicines but do not result in significant changes to medicines advertising policy. BCAP conducted an analysis of the HMRs to assess the need for regulatory change and/or technical updates to properly reflect the legislative framework and concluded that there was a need to consult on technical updates.

3. Consultation Responses

3.1 Outline

Total responses	**17**
Industry or parties representing industry	**11**
Interested parties (e.g. NGOs)	**2**
Members of the public	**2**
Government or regulatory bodies	**2**

3.2 Services Offering to Prescribe or Treat Remotely

Respondents (including trade associations, professional bodies and industry members) broadly supported the proposal. The one significant concern raised about the proposal was the effectiveness of BCAP rule 11.9 in setting a requirement for advertisers to hold suitable credentials to show the service offered was subject to appropriate regulatory safeguards.

3.3 Smoking Deterrents and Harm Reduction

The proposal was broadly supported with most respondents acknowledging the need to adapt to changes in the underlying medicines licensing framework. One respondent did, however, raise concerns over the need for the MHRA to approve individual advertisements to ensure that viewers and listeners were properly protected.

Several respondents raised a concern that the wording of the proposal was potentially unclear, because it might imply that the MHRA would license claims that smoking was "safer" while the habit was being reduced. Respondents pointed out that the new licensed indications for NRTs related only to harm reduction claims.

3.4 Technical Updates Reflecting Legislation

There were very few comments on the proposals reflecting their purely technical focus. One respondent queried Amendment 3A (BCAP) (References to the legislative framework) over the proposal to amend the reference to the Veterinary Medicines Regulations to state that they were "remade regularly" rather than annually.

4. Evaluation of Responses

4.1 Services offering to prescribe or treat remotely

As well as being in line with BCAP's general stance that legally available products and services should be able to advertise, BCAP notes the growth of professional, regulated operators providing services remotely via internet platforms. It considers that such developments, which it is satisfied are subject to appropriate regulatory safe-guards, undermine the premise of the existing rule that all services offering to prescribe or treat remotely could potentially cause harm to viewers and listeners. It is important to note BCAP intends the relaxation of the absolute prohibition to bring advertising for remote treatment services into line with its general approach to advertising for healthcare services. In that respect, the amended rule now requires advertisers to demonstrate that they hold suitable credentials in line with the strict criteria outlined in rule 11.9.

BCAP considers that no significant objections to the proposal were raised, either in response to the consultation itself or the pre-consultation. BCAP prepared the consultation proposal by seeking input from the key bodies responsible for regulating remote treatment services: the Department of Health, General Pharmaceutical Council, General Medical Council and Care Quality Commission.

4.2 Smoking deterrents and harm reduction

BCAP considers that, in line with the objective of ensuring that the Code accords with the underlying medicines licensing framework, the proposal is uncontroversial. However, BCAP acknowledges the various respondents' concerns over the clarity of the wording. As BCAP explained in the consultation document, it does not envisage that the MHRA will license NRT products to claim that smoking is "safer" whilst the habit is being reduced. The focus of BCAP's proposal is to ensure that harm reduction claims are not caught inadvertently by that description and prohibited under the existing rule. Nevertheless, BCAP agrees with the need to make the amended rule clearer and has therefore decided to alter the wording from that proposed in the consultation document.

4.3 Technical Updates Reflecting Legislation

BCAP notes the limited number of responses to the consultation and believes that the proposals are uncontroversial.

In response, the concern raised over the change to Section 11's description of the Veterinary Medicines Regulations, BCAP would point out that it sought the pre-consultation input of the Veterinary Medicines Directorate, the statutory body responsible for the regulations, which suggested that the amendment be made.

5. Consultation Outcome

5.1 BCAP's decision

BCAP has decided to amend the Code in line with the proposals in the consultation but subject to a minor amendment to clarify the wording of one of the proposals.

5.2 Services offering to prescribe or treat remotely

The existing rule states:

> 11.13.1 Advertisements must not contain offers to prescribe or treat remotely (including by phone, post, e-mail or fax). That does not preclude advertisements containing offers to distribute general information on health-related matters, such as leaflets or information packs.

This will be replaced by the following:

> 11.13.1 Advertisements must not contain offers to prescribe or treat remotely (including by phone, post, e-mail or by other means of an electronic communications network) unless the advertisers can demonstrate that the service offered complies with rule 11.9. Advertisements for medicinal products must not include such offers.
>
> That does not preclude advertisements containing offers to distribute general information on health-related matters, such as leaflets or information packs.

5.3 Smoking deterrents and harm reduction

The existing rule states:

> 11.18 Advertisements for smoking deterrents: […]
>
> 11.18.2 must not claim that smoking is safer while the habit is being reduced.

This will be replaced by the following (including a clarifying amendment to the proposals in the consultation document):

> 11.18 Advertisements for smoking deterrents: […]
>
> 11.18.2 must not claim that smoking is safer while the habit is being reduced. Harm reduction claims may be made if authorised by the MHRA.

5.4 Technical updates reflecting legislation

The technical changes to Section 11 (along with those in 5.2. and 5.3) are shown in a marked-up version included in Annex B.

5.5 Implementation of the changes

A full version of the new Section 11 is included in Annex A. The ASA will begin to enforce the changes to Section 11 from **Wednesday 18 June 2014**.

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