CAP Medicines Consultation: Regulatory Statement

Proposals for technical updates to the *Medicines, medical devices, health-related products and beauty products* section of the CAP 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 Technical Updates to the Medicines section of the Code

The Committee of Advertising Practice (CAP), author of the UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code) has decided to make several technical updates to the *Medicines, medical devices, health-related products and beauty products* section of the CAP Code ("Section 12") following a process of public consultation.

The updates respond to Human Medicines Regulations 2012 (HMRs), which consolidate the various pieces of UK medicines legislation, including the provisions governing the advertising of medicines, into one statutory instrument.

The HMRs do not represent a significant change in medicines advertising policy. However, this legislative development has given CAP a valuable opportunity to ensure that the Code is up to date and that the relevant rules appropriately mirror the underlying legislation.

This regulatory statement includes:

- Background to the issue and CAP's reasons for consulting
- A summary of consultation responses
- CAP's evaluation of responses
- Confirmation of CAP'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 CAP's response.

For further background and full details of each proposed amendment, including CAP's policy considerations, please refer to CAP's consultation document.

2. Background

2.1 New 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.

2.2 CAP's decision to consult

CAP conducted an analysis of the final draft of the consolidation of UK medicines regulations against the Code to assess the need for regulatory change and/or technical updates to properly reflect the legislative framework. The analysis also revealed several inconsistencies between the HMRs and the Code. CAP considered that the issues identified were related to the way in which the Code has been updated incrementally over time since the first European-wide framework for medicines regulation was introduced in the 1990s.

CAP considered that, although the HMRs did not constitute a significant change in advertising policy or practice, inconsistencies between certain rules and the statutory framework created a danger of confusion among Code users and the potential for the Code and decisions made by the ASA to be subject to challenge. CAP therefore decided to consult on a variety of proposed amendments to rectify the issues identified.

2.3 Policy objectives

In response to the potential problems identified, CAP considered that there was a need to propose amendments to the Code with the objectives of:

- Updating references to and providing greater clarity on the legislation underpinning Section 12;
- Amending rules to follow the wording and approach of the HMRs more closely; and
- Introducing, where necessary, new rules or new elements to rules to ensure that the Codes are in line with the relevant legislative frameworks.

3. Consultation Responses

3.1 Outline

Total responses	**9**
Industry or parties representing industry	5
Interested parties (e.g. NGOs)	1
Members of the public	2
Government or regulatory bodies	1

3.2 Summary

There were relatively few responses to the consultation.

The MHRA, as sectoral regulator responsible for the medicines advertising framework, signalled their general satisfaction with the proposed amendments. Several industry and industry representing parties also supported the proposals.

Although there were no broad or general objections to CAP's proposals, significant points were raised against various specific proposals:

- Concern was expressed over Amendment C (CAP) – Remote treatment and medicinal products – and whether the proposal to add a new rule prohibiting marketing communications for medicinal products from offering to provide a diagnosis or suggest a treatment by correspondence was worded in a manner that opposed the advertising of such services. The respondent was concerned that such an impact was in opposition to the government's policy approach on encouraging remote treatment.

- A respondent raised a concern over Amendment D (CAP) – Medicinal products and side-effects believing that advertisers should be allowed to make claims about the absence of side-effects where they held appropriate evidence.

- In relation to Amendment I (CAP) – Traditional herbal medicinal products – a respondent believed that CAP should be more consistent and hold all medicines to the same standards.

Respondents also made several comments and suggestions about the wording of the proposals. None expressed significant disagreement with the proposals: rather, respondents suggested amendments to ensure clarity of meaning and application.

4. Evaluation of Responses

4.1 General points

As the proposed amendments do not result in any changes to advertising policy and practice, CAP believes that the proposals are uncontroversial. It notes the small number of respondents to the consultation and that, for some proposals, respondents raised no significant points. However, given the aims of the project, it is important to ensure that the proposals are tightly worded and accord with the relevant provisions of the HMRs. With that in mind, CAP sought the view of the MHRA, as the responsible statutory body, from the earliest stages of the project and during the consultation. CAP notes the MHRA's positive response to the proposals.

4.2 Evaluation of significant points against the proposals

CAP does not consider that any of the significant points raised against the proposals give cause for their reconsideration.

In relation to the comments on:

- Amendment C (CAP), CAP is satisfied that the proposed addition of a new rule does not unduly restrict marketers of services offering remote treatment. It merely ensures that they do not contravene the prohibition in HMRs on promoting a medicinal product in conjunction with such services.

- Amendment D (CAP), CAP's proposal relates only to medicinal products, harmonising the Code with the HMRs, which prohibit any claims about products being without adverse reactions. Rule 12.9 permits advertisers to make claims that other products and therapies are guaranteed to work, absolutely safe or without side-effects provided that they hold evidence.

- Amendment I (CAP), CAP's objective was to propose changes to ensure the Code is in line with the wider statutory framework. CAP is satisfied that the proposed amendment achieves this objective. Concerns about the various standards applied in legislation to different categories of product go beyond the scope of the consultation.

4.3 Evaluation of significant comments related to the wording of proposals

CAP has made several minor amendments to the proposals to ensure clarity in its intended meaning. The amendments do not alter the intended effect of the proposals. Please see CAP's full evaluation of responses for details of the changes.

5. Consultation Outcome

5.1 CAP's decision

CAP has decided to amend the Code in line with the proposals in the consultation but subject to several minor amendments to the wording.

5.2 Amendments to the Code

The new version of Section 12 is included in Annex A and a marked-up version showing the finalised changes is included in Annex B.

5.3 Implementation of the changes

From **Wednesday 18 June 2014**, the ASA will begin to enforce against the changed rules in Section 12.

Contact us

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

www.cap.org.uk

Follow us: @CAP_UK