BCAP Medicines Consultation

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

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Legal, decent, honest and truthful

Contents

1. Executive Summary

The Broadcast Committee of Advertising Practice (BCAP), author of the UK Code of Broadcast Advertising (the BCAP Code), is consulting on several proposals to amend the *Medicines, medical devices, treatments and health* section ('Section 11') of the BCAP Code.

The consultation relates to three separate policy issues that have arisen since the last comprehensive review of the Code in 2009. The consultation considers proposals to:

- Amend the rule prohibiting advertisements for services offering remote treatment to allow adequately regulated services to advertise;
- Amend the rule on smoking deterrents to ensure that it does not conflict with medicines licence provisions that allow certain products to advertise on a harm reduction platform; and
- Make several technical updates to the code; primarily, in relation to the enactment of the Human Medicines Regulations 2012 (HMRs).

BCAP's objective is to prevent the inclusion of advertising in broadcast media, which may be misleading, harmful or offensive. It is particularly important that changes to Section 11 are given full consideration given the potential for irresponsible medicines and health-related advertising to cause harm to viewers and listeners.

The consultation will close at **5pm on Friday 25 October 2013**. For more information on the next steps see section 8 and, for full details of how to respond to the consultation, please see Annex 1.

2. Introduction to BCAP and the ASA

2.1 The Broadcast Committee of Advertising Practice

BCAP is the regulatory body responsible for maintaining the UK Code of Broadcast Advertising (the BCAP Code) under a contracting-out agreement with the Office of Communications (Ofcom).

Ofcom has statutory responsibility, under the Communications Act 2003, for maintaining standards in TV and radio advertisements. Ofcom entrusted BCAP and the broadcast arm of the ASA with the regulation of broadcast advertisements in 2004 in recognition of CAP and the ASA's successful regulation of non-broadcast advertisements for over 40 years and in line with better regulation principles.

The BCAP Code regulates all advertisements on television channels and radio stations licensed by Ofcom and all advertisements on Sianel Pedwar Cymru (S4C) and S4C digital, including teleshopping channels and any additional television service (including television text services and interactive television services). The BCAP Code is enforced against Ofcom-licensed broadcasters, Sianel Pedwar Cymru (S4C) and S4C digital. Broadcasters are required by the terms of their Ofcom licence, and, for S4C, by statute, to observe the standards set out in the BCAP Code.

The members that make up BCAP include broadcasters and trade associations representing advertisers, broadcasters and agencies. BCAP must seek advice on proposed Code changes from an expert consumer panel, the Advertising Advisory Committee (AAC). In accordance with Section 324 of the Communications Act 2003, BCAP must consult on proposed Code changes. BCAP strives to ensure that its rule drafting is transparent, accountable, proportionate, consistent and targeted where action is needed, in accordance with the Communications Act 2003. Ofcom must approve Code changes before BCAP implements them.

Information about BCAP and the AAC is available at www.cap.org.uk, which includes the BCAP Code.

2.2 The Advertising Standards Authority

The ASA is the independent body responsible for administering the BCAP Code and UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code) and ensuring that the self-regulatory system works in the public interest. The Codes require that all marketing communications are legal, decent, honest and truthful.

The ASA receives and investigates complaints from the public and industry. Decisions on investigated complaints are taken by the independent ASA Council. The ASA Council's adjudications are published on the ASA's website, www.asa.org.uk, and made available to the media. An Independent Review Procedure exists for interested parties who are dissatisfied with the outcome of a case.

If the ASA Council upholds a complaint, the advertisement must be withdrawn or amended. BCAP conducts compliance, monitoring and research to enforce the ASA Council's decisions.

The ASA's work in regulating broadcast advertising is funded by a levy on the cost of advertising space, administered by the Advertising Standards Board of Finance (Asbof) and the Broadcast Advertising Standards Board of Finance (Basbof). Both finance boards operate independently of the ASA to ensure there is no question of funding affecting the ASA's decision-making.

Information about the ASA, including the complaint-handling and investigations procedures and the ASA's independent review procedure, is available at www.asa.org.uk. Information about Asbof and Basbof is available at www.asbof.co.uk.

3. Regulatory Framework of the BCAP Code

3.1 Communications Act 2003

The Communications Act 2003 ('the Act') sets out provisions for the regulation of broadcasting and television and radio services, including provisions aimed at securing standards for broadcast advertisements. The most relevant standards objectives to this section are:

> 319(2)(a) that persons under the age of eighteen are protected;
>
> 319(2)(h) that the inclusion of advertising which may be misleading, harmful or offensive in television and radio services is prevented.

The Act requires Ofcom to set and, from time to time, review and revise a code containing standards for the content of broadcast advertisements carried by TV and radio services licensed under the Broadcasting Acts 1990 and 1996.

Ofcom has contracted-out its advertising standards codes function to BCAP under the Contracting Out (Functions Relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004. That function is exercised in consultation with and with the agreement of Ofcom. Provisions imposed on Ofcom by the Act are therefore relevant to BCAP.

3.2 Audio-Visual Media Services Directive (AVMS)

AVMS revises and updates the Television Without Frontiers (TVWF) Directive, which has regulated television broadcasting in the EU since 1989. The TVWF Directive applied to scheduled television broadcasting services only. AVMS also applies to some on-demand services. The Directive has specific provisions for teleshopping of medicinal products:

> Article 3(e)
> 1(f) audiovisual commercial communication for medicinal products and medical treatment available only on prescription in the Member State within whose jurisdiction the media service provider falls shall be prohibited;
>
> Article 14
> 2. Teleshopping for medicinal products which are subject to a marketing authorization within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (1), as well as teleshopping for medical treatment, shall be prohibited.

3.3 BCAP Code and medicines and health-related advertising

Section 11 of the BCAP Code covers advertising for a wide variety of products and services including products subject to statutory licensing or certification regimes, like

medicines, veterinary medicines, medical devices and homeopathic medicines, as well as services such as those offering complementary and alternative therapies.

Section 11 includes a variety of rules derived from statutory frameworks, such as those governing medicines and medical devices, alongside Code provisions intended to reflect the specific environment of broadcast advertising. This allows the BCAP Code to apply appropriate standards across the various sectors covered by Section 11, whilst conforming to specific legal requirements for certain products and services.

The most prominent statutory framework incorporated into Section 11 is that derived from European Directive 2001/83/EC (as amended), the *Community Code Relating to Medicinal Products for Human Use*, which lays down the requirements for the regulation of human medicinal products in all European member states. Title VIII of the Directive concerns "The Advertising of Medicinal Products for Human Use". The Directive is incorporated into UK law by regulations made under the Medicines Act 1968.

The Medicines and Healthcare product Regulatory Agency (MHRA), an executive agency of the Department of Health, is the statutory body responsible for the administration and enforcement of the regulations governing medicines advertising.

Another framework is that which governs veterinary medicines. Directive 2001/82/EC (as amended by Directive 2004/28/EC) the *Community code relating to veterinary medicinal products*, lays down the requirements for the regulation of veterinary medicinal products in all European member states. This has been implemented in the UK via the Veterinary Medicines Regulations, which are the responsibility of the Veterinary Medicines Directorate (VMD). The Veterinary Medicines Regulations are revoked and remade regularly. The VMD is an executive agency of the Department of the Environment, Food and Rural Affairs (DEFRA).

3.4 Human Medicines Regulations 2012

The HMRs implement Title VIII of Directive 2001/83/EC on the advertising of medicines for human use. The HMRs are the culmination of the MHRA's consolidation and review of UK medicines legislation. Following the 1968 Medicines Act there have 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. In broadcast advertising under its contracting out agreement with Ofcom, the ASA is obliged to investigate complaints about broadcast advertisements as set out in Regulation 314.

4. BCAP's Consultation

4.1 Policy objectives

BCAP's general policy objectives accord with those of the Communications Act 2003 noted above. Furthermore, BCAP is mindful of its specific responsibilities under its contracting out agreement with Ofcom derived from legislative framework for medicines advertising; in particular, the requirement for the ASA to consider certain types of complaint about medicines advertising.

With regard to Section 11 of the Code, BCAP acknowledges the potential for medicines and health-related advertising to cause harm to viewers and listeners. Products and services covered by Section 11 will in many instances relate to medical matters where viewers and listeners should expect to receive responsible and accurate information. As such, BCAP recognises the importance of adhering to the standards set out in the statutory frameworks governing the advertising of products like medicines in broadcast media, as well as the need to include other proportionate and targeted rules to protect viewers and listeners from advertising approaches that are likely to cause harm.

BCAP also intends its rules to be transparent, accountable, proportionate, consistent, targeted only where regulation is needed and written so that the rules are easily understood, easily implemented and easily enforced.

4.2 Structure of the consultation

The proposed changes to the BCAP Code are outlined in the following sections (5, 6 and 7 respectively). They are laid out in three parts, covering the three issues under consideration:

Part 1: Services Offering to Prescribe or Treat Remotely
Part 2: Smoking Deterrents and Harm Reduction
Part 3: Technical Updates Reflecting Legislation

Respondents are reminded that, although they all relate to Section 11, the issues are being considered independently.

4.3 Using this consultation document

The proposed amendments to the Code are set out in sections 5, 6 and 7 below. Each is identified by a number, corresponding to one of the three parts outlined above, and a letter (e.g. 'Amendment 3B').

The amendments are suffixed with "(BCAP)" to ensure that there is no confusion with the corresponding Committee of Advertising Practice (CAP) consultation on the medicines section of the CAP Code, which covers some of the same issues as BCAP's consultation. Respondents should ensure that they are aware of this distinction and that they mark their responses clearly, particularly, if they intend to respond only one consultation.

For each proposed amendment, BCAP has outlined the issue or issues that have given it cause to consider amending the Code, along with the reasons for the decision to consult and the proposed amendment(s) to the Code.

Along with the reasoning outlined in each part of the consultation, respondents should also have regard to the legislative framework outlined in section 3 and BCAP's wider objectives and considerations outlined above and in this section.

The wording of the proposed amendments, along with the consultation questions are contained in the boxes at the end of each part.

- Rules and text within Section 11 that are affected by the proposed amendments are included in the boxes.
- The proposed changes are shown in darker text; deleted wording is struck-through.
- Wording that is unaffected is shown in lighter text.
- A full marked-up version of the amended Section 11 is included in Annex 2.

Please respond to each question in turn referring to the proposed amendments by their number and letter. For convenience, respondents will find a single list of the consultation questions in Annex 3 to assist in drafting their response.

4.4 Setting expectations

BCAP is conducting this consultation in order to address three policy issues that have arisen since the last comprehensive review of the Code. While it welcomes a broad range of comments from any party wishing to respond, BCAP does not consider that this process should serve as an opportunity for a general review of Section 11.

For the avoidance of doubt, BCAP will not consider comments that fall outside the scope of the proposals outlined below.

5. Part 1: Services Offering to Prescribe or Treat Remotely

5.1 Policy background

In 2009, BCAP considered a proposal to remove the restriction prohibiting services offering to prescribe or treat remotely from advertising on TV and Radio. The restriction, now rule 11.13.1 of the BCAP Code, is based on the need to have added safeguards against poorly regulated or potentially unscrupulous services in more penetrative advertising media. The rule is broadcast-specific and remote treatment services may advertise in other media.

The growth of mainstream services utilising electronic communications networks to engage with consumers, such as online pharmacies, has led to questions about the appropriateness of such a strong prohibition. BCAP notes, for instance, that online pharmacies are subject to a developed system of regulatory oversight based on a statutory framework. Furthermore, the legislative framework for medicines, Regulation 286 (Material relating to diagnosis) of the HMRs, states only that advertising for medicinal products may not include such offers:

> (2) A person may not, in particular, publish an advertisement relating to a medicinal product that offers to provide a diagnosis or suggest a treatment by post or by means of an electronic communications network within the meaning of the Communications Act 2003.

At the time, BCAP decided not to formally consider a relaxation of the rule on the advice of the relevant statutory and professional regulators who pointed out that significant changes to the regulatory framework were underway. The Healthcare Commission was in the process of being replaced by the Care Quality Commission in its role regulating healthcare services and the regulation of pharmacists, pharmacy technicians and pharmacy premises was in the process of passing from the Royal Pharmaceutical Society of Great Britain to the newly constituted General Pharmaceutical Council (GPhC).

In light of the changes to the regulatory framework, BCAP decided to postpone its consideration in order to allow the new regulatory framework to establish itself before addressing the matter through a formal process.

5.2 BCAP's decision to consider amending the Code

Since 2009, several industry parties have renewed calls for BCAP to reconsider rule 11.13.1. BCAP considers that there are grounds to examine whether the prohibition is excessive given developments in the healthcare market brought about by the internet and on the basis that the standard required by medicines law is lower. In coming to its decision, BCAP pre-consulted the various statutory and professional bodies responsible for regulating health professionals and services, such as online pharmacies; the Department of Health, GPhC, General Medical Council and Care Quality Commission.

Following the pre-consultation, BCAP is satisfied that there are no fundamental obstacles to formally considering a proposal to relax the rule. BCAP considers that it is in keeping with the general approach of the Code to allow services, which are

appropriately regulated to ensure necessary standards, may be allowed to advertise.

5.3 Proposal: Amendment 1A (BCAP)

BCAP proposes an amendment to relax the prohibition on services offering to prescribe or treat remotely. The proposal would result in services, such as online pharmacies, being able to advertise to TV and radio provided that they are able to satisfy the provisions of rule 11.9. Rule 11.9 is the basis of BCAP's general approach to other services offering medical treatment; that they may advertise, provided that they can satisfy the ASA that they have suitable credentials to provide the service. BCAP intends to effect of the proposal to permit advertising by appropriately regulated services, whilst maintaining prohibition on advertising by unsuitable services.

BCAP Code rule 11.9 states:

> Services including Clinics, Establishments and the like Offering Advice on, or Treatment in, Medical, Personal or other Health Matters – Advertisements are acceptable only if the advertiser can provide suitable credentials, for example, evidence of: relevant professional expertise or qualifications; systems for regular review of their skills and competencies and suitable professional indemnity insurance covering all services provided; accreditation by a professional or regulatory body that has systems for dealing with complaints and taking disciplinary action and has registration based on minimum standards for training and qualifications.

The proposed amendment also includes a provision to ensure that the relaxation continues to comply with the HMRs Regulation 286, which prohibits offers to prescribe or treat remotely in advertisements for medicines.

Proposed Wording	11.13.1 Advertisements must not contain offers to prescribe or treat remotely (including by phone, post, e-mail or ~~fax~~ 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.

Question 1	**Do you agree the proposal to amend rule 11.13.1 of Section 11? If not, please explain why.**
Question 2	**Do you agree to the wording of the proposed amendment? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

6. Part 2: Smoking Deterrents and Harm Reduction

6.1 Policy background

In 2010, the MHRA licensed nicotine replacement therapy (NRT) products on a harm reduction platform. On public health grounds, they accepted that such products could reduce harm to smokers, while the habit is being reduced. This moves away from the previous general approach to smoking cessation, which held that no level of smoking could be considered preferable.

In line with wider public health advice, BCAP Code rule 11.18.2 prohibits claims that smoking less can be safer, whether explicit or implied. It is a general rule covering a wide variety of smoking deterrents, from licensed medicines to various types of therapy, and is intended to ensure that advertisements present responsible messages in relation to smoking.

6.2 BCAP's decision to consider amending the Code

BCAP is concerned that the present rule could, in some circumstances, prohibit advertisements for smoking deterrents from making harm reduction claims for products licensed by the MHRA to do so. BCAP acknowledges that advertisers are highly unlikely to be permitted to state in an advertisement that an NRT product makes smoking "safer". However, as the Code requires the consideration of claims, whether explicit or implied, a harm reduction claim might have such an implication and thereby breach rule 11.18.2 as presently drafted. The rule requires that advertisements for smoking deterrents:

> must not claim that smoking is safer while the habit is being reduced.

As well as potentially contradicting the MHRA's position on NRT, the present rule is not consistent with other provisions of the BCAP Code; principally, rule 11.19, which require advertisers to conform to the terms of the licence. BCAP therefore considers that it is necessary to amend the rule in order to avoid such potential conflicts.

6.3 Proposal: Amendment 2A (BCAP)

To resolve this issue, BCAP proposes to add an exemption to the rule in order permit advertising on a harm reduction platform subject to MHRA approval.

Proposed Wording	11.18 Advertisements for smoking deterrents: […] 11.18.2 must not claim that smoking is safer while the habit is being reduced, unless authorised to do so by the MHRA.

Question 3	**Do you agree with the proposal to amend rule 11.18.2 of Section 11? If not, please explain why.**
Question 4	**Do you agree to the wording of the proposed amendment? If not, please explain why and include any alternative wording that you consider to be**

more appropriate.

7. Part 3: Technical Updates Reflecting Legislation

7.1 Policy background

The present regulations governing medicines advertising, the Human Medicines Regulations 2012 (HMRs), came into force in August 2012.

The HMRs are the culmination of the MHRA's work to consolidate UK medicines legislation. Following the 1968 Medicines Act there have 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 and do not represent a significant change in medicines advertising policy. However, they do make the regulations governing medicines advertising more clear and accessible.

7.2 BCAP's decision to consider amending the Code

BCAP conducted an analysis of the final draft of the consolidated regulations against the Code to assess any need for regulatory change and technical updates to ensure that Section 11 properly explains its relationship to the legislative framework. Although BCAP found no cause to consider regulatory change, it did identify several technical points that should be addressed through minor amendments to the Code. Furthermore, it identified other minor points, relating in particular to veterinary medicines, where greater clarity could be provided to Code users on the various statutory frameworks that underpin Section 11.

BCAP pre-consulted with the MHRA, as the statutory body responsible for the HMRs and various other statutory frameworks. It also pre-consulted the VMD as the statutory body responsible for the veterinary medicines framework. They considered that there are no fundamental obstacles to a BCAP consultation on the proposals outlined below.

7.3 Amendment 3A (BCAP) – References to the legislative framework

To resolve these issues, BCAP proposes several technical amendments to properly reflect the legislation upon which many of the medicines-related rules in Section 11 are based and to provide greater clarity, in particular, in relation to the application of Section 11 to veterinary medicines.

Proposed Wording	
	Law Title VIII of European Directive 2001/83/EC (as amended) ~~as amended by Directive 2004/27/EC~~ concerns "The Advertising of Medicinal Products for Human Use" and has been implemented in the UK by the Human Medicines Regulations 2012 ~~The Medicines (Advertising) Regulations 1994 and The Medicines (Monitoring of Advertising) Regulations 1994 (both as amended)~~. ASA (Broadcast) is obliged to consider complaints about breaches of any of Regulations 286 to 290 ~~Regulation 9 of the Advertising Regulations~~, which have ~~has~~ been incorporated into these rules. With the introduction of new or changed products, the diverse licensing requirements ~~of the Medicines Act 1968~~ and changes in medical opinion, this Code cannot provide a complete guide to all requirements for health claims or the advertising of products or classes of medicines and treatments. Advertisements for products subject to licensing under the ~~Medicines Act 1968~~ Human Medicines Regulations 2012 must comply with the requirements of the ~~Act~~ Regulations~~. That includes regulations made under the Act~~ Advertisements must also comply with any conditions contained in the marketing authorisation, certificate, licence or traditional herbal registration for the advertised product. For more information on medicinal products and treatments, go to: www.mhra.gov.uk. The rules governing the advertising of medicines, treatments, medical devices and health claims are set out below; they apply also to advertisements for veterinary products and services. Directive 2001/82/EC on the Community code relating to veterinary medicinal products (as amended by Directive 2004/28/EC), which has been implemented in the UK via The Veterinary Medicines Regulations, contains provisions relating to the advertising of such products. The Veterinary Medicines Regulations are revoked and remade regularly ~~annually~~. For more information on veterinary medicinal products and treatments, please see Veterinary medicines Guidance Note 4, Controls on Advertising (http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx) The European legislation governing medical devices is made up of Directive 90/385/EEC relating to active implantable medical devices, Directive 93/42/EEC on medical devices (as amended by Directive 2000/70/EC) and Directive 98/79/EC on in-vitro diagnostic medical devices. The MHRA is the body responsible for ensuring medical devices work and are safe. Generally, all devices covered by the scope of the relevant Directive should carry a CE mark, which is a public representation of the manufacturer's claim that its device satisfies the relevant Essential Requirements of the Directives, is fit for its intended purpose and, if required, has been independently assessed by a Notified Body. For more information, go to: www.mhra.gov.uk.

Question 5	**Do you agree with the proposal to amend the "Law" sub-section of Section 11? If not, please explain why.**
Question 6	**Do you agree to the wording of the proposed amendments? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

7.4 Proposal: Amendment 3B (BCAP) – References to European Medicines Agency (EMA) and Veterinary Medicines Directorate (VMD)

Alongside the licensing function of the MHRA, medicines licences can also be granted by the European Commission, under the auspices of the EMA, that are valid across EU jurisdictions in parallel to national schemes. Furthermore, the VMD are responsible for granting licences for veterinary medicinal products.

BCAP considers that the various references to licensing requirements are inconsistent or unclear. The "Background" sub-section and rules 11.4 and 11.19 do not make sufficiently clear the roles of the EMA and VMD in granting medicines licenses.

To resolve these issues, BCAP proposes amendments to avoid any potential ambiguity over which bodies are responsible for granting medicines licenses necessary for a product to be advertised. BCAP also proposes to amend all relevant references to ensure the EMA is referred to correctly after the change in its initialism from "EMEA" to "EMA".

Proposed Wording	**Background** The rules in this section are designed to ensure that advertisements that include health claims (please see Section 13 for health claims made on foods) and advertisements for medicines, medical devices and treatments receive the necessary high level of scrutiny. Health claims may, for example, relate to the therapeutic or prophylactic effects of products, including toiletries and cosmetics. The rules apply to advertisements and not the products or services, which are regulated by health regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), Veterinary Medicines Directorate (VMD), the European Medicines Agency ~~(EMEA)~~ (EMA), the Care Quality Commission and the Department of Health. Advertisements for those products or services must comply with the rules and professional codes of conduct of relevant professional bodies. […] 11.4 Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA, the VMD or under the auspices of the EMA ~~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. […] 11.19 Medicines must have a licence from the MHRA, the VMD or under the auspices of the EMA before they are advertised. Advertisements for medicinal products must conform with the licence. Advertisements must not suggest that a product is "special" or "different" because it has been granted a licence ~~from the MHRA~~. For the avoidance of doubt, by conforming with the product's indicated use, an advertisement would not breach rule 11.3.

Question 7	**Do you agree with the proposal to amend the "Background" sub-section and rules 11.4 and 11.19 of Section 11? If not, please explain why.**
Question 8	**Do you agree to the wording of the proposed amendments? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

8. Next Steps

BCAP is committed to considering all responses carefully and with an open mind.

Given the sector-specific nature of this consultation, BCAP would in particular welcome responses from stakeholders with an interest or expertise in matters related to medicines and healthcare related products and services. Responses from other stakeholders and members of the public are also welcome.

Responses have been invited from a cross-section of interested parties representing both consumers and the industry. Information on how to respond to this consultation can be found in Annex 1.

The following summarises the consultation process and subsequent stages of BCAP's consideration of the proposed changes to the Code:

- The consultation will run for eight weeks, with a two week extension owing to the summer period; it will close at **5pm on Friday 25 October 2013**.
- BCAP will consider each response carefully and evaluate all significant points explaining the reasons behind the decisions it makes.
- The consultation evaluation will be published on the BCAP website when the outcome of the consultation is announced.

9. Annex 1: Responding to this Consultation

9.1 How to respond

BCAP invites written comments, including supporting evidence on the proposals contained in this document, by **5pm on Friday 25 October 2013**.

When responding, please state if you are doing so as an individual or a representative of an organisation. Also, please make clear what your individual interest is or who your organisation represents. It will be helpful if you explain fully and clearly why you hold your opinion.

Responses via email with attachments in Microsoft Word format are preferred to assist in the processing of responses.

Please send your response to andrewt@cap.org.uk.

If you are unable to reply by email, you may submit your response by post or fax (+44 (0)20 7404 3404), marked with the title of the consultation, to:

BCAP Medicines Consultation
Code Policy Team
Committee of Advertising Practice
Mid City Place
71 High Holborn
London WC1V 6QT

9.2 Confidentiality

BCAP considers that everyone who is interested in the consultation should see the consultation responses. In its evaluation document, BCAP will publish all the relevant significant comments made by respondents and identify all non-confidential respondents. The evaluation will be published with the outcome of the consultation.

All comments will be treated as non-confidential unless you state that all or a specified part of your response is confidential and should not be disclosed. If you reply by email or fax, unless you include a specific statement to the contrary in your response, the presumption of non-confidentiality will override any confidentiality disclaimer generated by your organisation's IT system or included as a general statement on your fax cover sheet.

If part of a response is confidential, please put that in a separate annex so that non-confidential parts may be published with your identity. Confidential responses will be included in any statistical summary of numbers of comments received.

10. Annex 2: Mark-up of the Proposed Changes to the Code

Medicines, Medical Devices, Treatments and Health

Background

The rules in this section are designed to ensure that advertisements that include health claims (please see Section 13 for health claims made on foods) and advertisements for medicines, medical devices and treatments receive the necessary high level of scrutiny. Health claims may, for example, relate to the therapeutic or prophylactic effects of products, including toiletries and cosmetics.

Amendment 3B (BCAP)

The rules apply to advertisements and not the products or services, which are regulated by health regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), Veterinary Medicines Directorate (VMD), the European Medicines Agency ~~(EMEA)~~ (EMA), the Care Quality Commission and the Department of Health. Advertisements for those products or services must comply with the rules and professional codes of conduct of relevant professional bodies.

Medical advisory panels

For television advertisements, Clearcast retains a panel of consultants to advise it on health and medical aspects of products or services before they are advertised. For information, see "Contact us" at www.clearcast.co.uk.

For radio advertisements, the RACC retains a panel of consultants to advise it on health and medical aspects of advertising. For information, see "Services" at www.racc.co.uk.

The ASA or BCAP may seek a medical opinion if there is a significant challenge to an advertisement that has been accepted by a broadcaster on the advice of a member of the panels.

Law

Amendment 3A (BCAP)

Title VIII of European Directive 2001/83/EC (as amended) ~~as amended by Directive 2004/27/EC~~ concerns "The Advertising of Medicinal Products for Human Use" and has been implemented in the UK by the Human Medicines Regulations 2012 ~~The Medicines (Advertising) Regulations 1994 and The Medicines (Monitoring of Advertising) Regulations 1994 (both as amended)~~. ASA (Broadcast) is obliged to consider complaints about breaches of any of Regulations 286 to 290 ~~Regulation 9 of the Advertising Regulations~~, which have ~~has~~ been incorporated into these rules.

With the introduction of new or changed products, the diverse licensing requirements ~~of the Medicines Act 1968~~ and changes in medical opinion, this Code cannot provide a complete guide to all requirements for health claims or the advertising of products or classes of medicines and treatments.

Amendment 3A (BCAP)

Advertisements for products subject to licensing under the ~~Medicines Act 1968~~ Human Medicines Regulations 2012 must comply with the requirements of the ~~Act~~ Regulations~~. That includes regulations made under the Act~~ Advertisements must also comply with any conditions contained in the marketing authorisation, certificate, licence or traditional herbal registration for the advertised product.

For more information on medicinal products and treatments, go to: www.mhra.gov.uk.

The rules governing the advertising of medicines, treatments, medical devices and health claims are set out below; they apply also to advertisements for veterinary products and services. Directive 2001/82/EC on the Community code relating to veterinary medicinal products (as amended by Directive 2004/28/EC), which has

been implemented in the UK via The Veterinary Medicines Regulations, contains provisions relating to the advertising of such products. The Veterinary Medicines Regulations are revoked and remade regularly ~~annually~~.

Amendment 3A (BCAP)

For more information on veterinary medicinal products and treatments, please see Veterinary medicines Guidance Note 4, Controls on Advertising (http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx)

The European legislation governing medical devices is made up of Directive 90/385/EEC relating to active implantable medical devices, Directive 93/42/EEC on medical devices (as amended by Directive 2000/70/EC) and Directive 98/79/EC on in-vitro diagnostic medical devices. The MHRA is the body responsible for ensuring medical devices work and are safe. Generally, all devices covered by the scope of the relevant Directive should carry a CE mark, which is a public representation of the manufacturer's claim that its device satisfies the relevant Essential Requirements of the Directives, is fit for its intended purpose and, if required, has been independently assessed by a Notified Body. For more information, go to: www.mhra.gov.uk.

Definition

For the purposes of this section, "licence" includes certificate, authorisation or registration.

Rules

11.1 **Radio Central Copy Clearance** – Radio broadcasters must ensure advertisements subject to this section are centrally cleared.

11.2 If they are necessary for the assessment of claims, broadcasters must, before the advertisement is broadcast, obtain generally accepted scientific evidence and independent expert advice.

11.3 Advertisements must not discourage essential treatment for conditions for which medical supervision should be sought. For example, they must not offer specific advice on, diagnosis of or treatment for such conditions unless that advice, diagnosis or treatment is conducted under the supervision of a suitably qualified health professional (see rule 11.9). That does not prevent advertising for spectacles, contact lenses or hearing aids.

Amendment 3B (BCAP)

11.4 Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA, the VMD or under the auspices of the EMA ~~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.

11.5 These are not acceptable in advertisements for medicinal products:

11.5.1 Presentations, by doctors, dentists, veterinary surgeons, pharmaceutical chemists, nurses, midwives and the like that imply professional advice or recommendation

11.5.2 statements that imply professional advice or recommendation by people who are presented, whether directly or by implication, as being qualified to give that advice or recommendation

11.5.3 references to approval of, or preference for, any relevant product or their use by the professions covered by rule 11.5.1.

11.6 Advertisements other than those for medicinal products may feature or refer to health professionals covered by rule 11.5.1, if those professionals are suitably qualified in the relevant subject.

11.7 Unless it is obvious from the context, advertisements that include a health professional must make clear if he or she has a direct financial interest, or equivalent reciprocal interest, in the sale of the advertised product or service.

11.8 Testimonials or endorsements by health professionals must be genuine and supported by documentary evidence. Fictitious testimonials must not be presented as genuine. Any statement in a testimonial that is likely to be interpreted as a factual claim must be substantiated.

11.9 **Services including Clinics, Establishments and the like Offering Advice on, or Treatment in, Medical, Personal or other Health Matters** – Advertisements are acceptable only if the advertiser can provide suitable credentials, for example, evidence of: relevant professional expertise or qualifications; systems for regular review of their skills and competencies and suitable professional indemnity insurance covering all services provided; accreditation by a professional or regulatory body that has systems for dealing with complaints and taking disciplinary action and has registration based on minimum standards for training and qualifications.

11.10 Advertisements for hypnosis-based procedures (including techniques commonly referred to as hypnotherapy), psychiatry, psychology, psychoanalysis or psychotherapy are acceptable subject to rule 11.9. Broadcasters must take particular care over advertisements for publications employing those techniques.

11.11

11.11.1 Advertisements for services offering advice on unplanned pregnancy must make clear in the advertisement if the service does not refer women directly for a termination. Given that terminations are lawful only in some circumstances, and are subject to particularly stringent requirements in Northern Ireland, advertisers may wish to seek legal advice before advertising.

11.11.2 **Radio Central Copy Clearance** – Radio broadcasters must ensure advertisements for family planning centres are centrally cleared.

11.12 **Television only** – Teleshopping for these products or services is not acceptable:

11.12.1 medicinal products that are for human use and that are subject to a marketing authorisation within the meaning of Directive 2001/83/EC (as amended by Directive 2004/27/EC) and are on the General Sale List (GSL) as a pharmacy medicine (P) or as a prescription-only medicine (POM)11.12.2 veterinary medicinal products that are subject to a marketing authorisation within the meaning of Directive 2001/82/EC (as amended by Directive 2004/28/EC) and are available as an authorised veterinary medicine on the General Sales List (AVMGSL) as a non-food animal medicine from a veterinarian, pharmacist or suitably qualified person or as a prescription-only medicine from a veterinarian (POM-V) or from a veterinarian, pharmacist or suitably qualified person (POM-VPS)

11.12.3 medical treatments for humans or animals.

11.13 Broadcasters may accept advertisements for services offering remote personalised advice on medical or health matters only if all staff providing that advice are suitably qualified and subject to regulation by a statutory or recognised medical or health professional body and the advice given is in accordance with its relevant professional codes of conduct (see rule 11.9).

11.13.1 Advertisements must not contain offers to prescribe or treat remotely (including by phone, post, e-mail or ~~fax~~ 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.

Amendment 1A (BCAP)

That does not preclude advertisements containing offers to distribute general information on health-related matters, such as leaflets or information packs.

11.14 No advertisement may encourage indiscriminate, unnecessary or excessive use of products or services covered by this section.

11.15 Unless allowed by a product licence, words, phrases or illustrations that claim or imply the cure of an ailment, illness, disease or addiction, as distinct from the relief of its symptoms, are unacceptable.

11.16 Unless authorised by the relevant product licence, the word "tonic" is not acceptable in advertisements that make health claims. Claims must not suggest that a product has tonic properties. That does not prevent the use of the word "tonic" in the description "Indian tonic water" or "quinine tonic water".

11.17 Jingles may be used. Those that incorporate a medical or health claim must be substantiated.

11.18 Advertisements for smoking deterrents:

11.18.1 must make clear that the indispensable factor in giving up smoking is willpower

Amendment 2A (BCAP)

11.18.2 must not claim that smoking is safer while the habit is being reduced, unless authorised to do so by the MHRA.

Medicines

11.19 Medicines must have a licence from the MHRA, the VMD or under the auspices of the EMA before they are advertised. Advertisements for medicinal products must conform with the licence. Advertisements must not suggest that a product is "special" or "different" because it has been granted a licence ~~from the MHRA~~. For the avoidance of doubt, by conforming with the product's indicated use, an advertisement would not breach rule 11.3.

Amendment 3B (BCAP)

11.20 Advertisements for medicinal products which include a product claim (including legible on-pack product claims within a pack shot) must include this information:

11.20.1 the name of the product
11.20.2 the name of the active ingredient, if it contains only one
11.20.3 relevant wording such as "always read the label" or "always read the leaflet"
11.20.4 the indication (what the product is for).

Advertisements for traditional herbal medicinal products and homeopathic medicinal products must include mandatory information, which can be found in the MHRA Blue Guide at www.mhra.gov.uk.

11.21 Advertisements for these are not acceptable:

11.21.1 medicinal products or medical treatments available only on prescription

11.21.2 Products for the treatment of alcohol or substance misuse or dependence. An exception is made for smoking deterrents (see rule 11.18).

11.22 No advertisement may suggest that a medicinal product is a foodstuff, cosmetic or other consumer product.

11.23 No advertisement for a medicinal product may claim its effects are guaranteed. That does not prevent the offering of refunds, if the advertisement does not suggest that efficacy is guaranteed.

11.24 No advertisement for a medicinal product or treatment may be directed at children. See also Section 5: Children and Section 32: Scheduling.

11.25 Advertisements must not, without good reason, make the audience anxious that they are or might be suffering from disease or ill-health or might do so if they do not respond to the advertisement.

11.25.1 Advertisements must not falsely suggest that a product is necessary for the maintenance of physical or mental health or that health could be enhanced by taking the product or affected by not taking it.

11.26 Advertisements must not, in improper, alarming or misleading ways, use images of changes in the human body caused by disease, injury or a medicinal product.

11.27 No advertisement for a medicinal product or treatment may include a recommendation by a person well-known in public life, sport, entertainment or similar or be presented by such a person. That includes persons corporate as well as singular and would prohibit, for example, recommendations by medical charities, patient groups and health or sport organisations.

11.28 No advertisement for a medicinal product may refer in improper, alarming or misleading terms to claims of recovery.

11.29 Advertisements for medicinal products must not contain material that could, for example, by description or detailed representation of a case history, lead to a wrong self-diagnosis.

11.30 Although it may refer to the likely absence of a specific side effect, for example, “unlikely to cause drowsiness”, no advertisement for a medicinal product may suggest that a product has no side effects.

11.31 No advertisement for a medicinal product or treatment may suggest that the effects are better than, or equivalent to, those of another identifiable medicinal product or treatment.

11.32 No advertisement for a medicinal product may suggest that the safety or efficacy of the product is due to it being “natural”.

11.33 Only homeopathic medicinal products that are registered in the UK may be advertised. Mandatory information for homeopathic advertisements can be found in the MHRA Blue Guide at www.mhra.gov.uk.

11.34 A tension headache is a recognised medical condition; analgesics may be advertised for the relief of pain associated with that condition but no

advertisement for a simple or compound analgesic may claim the direct relief of tension or refer to depression.

11. Annex 3: Summary List of the Consultation Questions

Amendment 1A (BCAP)	**Question 1**	**Do you agree the proposal to amend rule 11.13.1 of Section 11? If not, please explain why.**
	Question 2	**Do you agree to the wording of the proposed amendment? If not, please explain why and include any alternative wording that you consider to be more appropriate.**
Amendment 2A (BCAP)	**Question 3**	**Do you agree with the proposal to amend rule 11.18.2 of Section 11? If not, please explain why.**
	Question 4	**Do you agree to the wording of the proposed amendment? If not, please explain why and include any alternative wording that you consider to be more appropriate.**
Amendment 3A (BCAP)	**Question 5**	**Do you agree with the proposal to amend the "Law" sub-section of Section 11? If not, please explain why.**
	Question 6	**Do you agree to the wording of the proposed amendments? If not, please explain why and include any alternative wording that you consider to be more appropriate.**
Amendment 3B (BCAP)	**Question 7**	**Do you agree with the proposal to amend the "Background" sub-section and rules 11.4 and 11.19 of Section 11? If not, please explain why.**
	Question 8	**Do you agree to the wording of the proposed amendments? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

Contact us

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