

SECTION 11: MEDICINES, MEDICAL DEVICES, TREATMENTS, AND HEALTH

Question 59: Given BCAP's policy consideration, do you agree that rule 11.9 (Services including Clinics, Establishments and the like Offering Advice on, or Treatment in, Medical, Personal or other Health Matters) should be included in the proposed BCAP Code? If your answer is no, please explain why.

<i>Responses received in favour of BCAP's proposal from:</i>	<i>Summaries of significant points:</i>	<i>BCAP's evaluation of those points and action points:</i>
<p>Advertising Association; Changing Faces; Charity Law Association; An organisation; IPA; An organisation; Proprietary Association of Great Britain; An organisation; An organisation</p>	<p>1.1 Respondents consider rule 11.9 should be included in the proposed BCAP Code.</p>	<p>1.1 BCAP agrees</p>
<p>General Medical Council</p>	<p>1.2 It would be helpful to ensure that services can provide credentials for themselves (e.g. registration with the relevant regulatory or inspection body) and the staff who will be offering advice or treatment. Certainly services should be expected to make this information accessible and readily available to</p>	<p>1.2 BCAP does not regulate the services covered by this section of the Code. The ASA and BCAP can request evidence of qualifications etc via investigations and compliance work. The RACC and Clearcast will request evidence of suitable credentials and evidence of registration with a</p>

	<p>potential clients. As we have commented on rule 12.3 of the CAP code, we expect doctors providing 'remote' services to provide their name and registration number to potential patients/clients. Ads should include essential information, such as whether a service is registered.</p>	<p>regulatory body etc prior to broadcast. The Department of Health (DH) provides advice on cosmetic procedures including a checklist of questions consumer should ask prior to individual treatment, particularly physically invasive treatment. The Medicines, Treatments, Devices and Health section contains a link to the DH website</p> <ul style="list-style-type: none"> • http://www.dh.gov.uk/en/Publichealth/CosmeticSurgery/DH_913 • http://www.dh.gov.uk/en/Publichealth/CosmeticSurgery/DH_4124056 <p>BCAP considers requiring registration numbers or similar in broadcast advertisements is not particularly helpful to the audience, as the audience is unlikely be in a position to utilise the information. BCAP considers including information that is required by other regulators is an overly burdensome requirement on broadcasters and would result in the ASA enforcing requirements outside its remit.</p>
<p><i>Responses received against BCAP's proposal:</i></p>	<p><i>Summaries of significant points:</i></p> <p>No significant comments received</p>	<p><i>BCAP's evaluation of those points and action points:</i></p>
<p>Question 60: Given BCAP's policy consideration, do you agree that rule 11.4 (medicinal claims for a medicinal product or device) should be included in the proposed BCAP Code? If your answer is no, please explain why.</p>		
<p><i>Responses received</i></p>	<p><i>Summaries of significant points:</i></p>	<p><i>BCAP's evaluation of those points and action</i></p>

<p><i>in favour of BCAP's proposal from:</i></p> <p>Advertising Association; ASDA; Changing Faces; Charity Law Association ; IPA; Proprietary Association of Great Britain; An organisation; An organisation</p>	<p>2.1 Respondents agree that rule 11.4 should be included in the proposed BCAP Code.</p>	<p><i>points:</i></p>
<p><i>Responses received against BCAP's proposal:</i> Alliance Boots</p>	<p><i>Summaries of significant points:</i></p> <p>2.2 The definition provided in 11.4 is not accurate. It does not reflect the definitions in the Medicines Act or that contained in the Medical Devices Regulations. It may be helpful to include it in the Code from the point of view of providing assistance to people assessing what is a medicinal product, however as it does not accurately reflect the law, we suggest that it is not used.</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>2.2 As the respondent did not clarify how the proposed rule is inaccurate, BCAP is unable to comment further on this response.</p> <p>BCAP sought advice on rule 11.4, in particular its accuracy and applicability to medical devices and cosmetics. BCAP proposes:</p> <p>11.4 Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA or EMEA, or for a CE-marked medical device. A medicinal claim is a claim that a product or its constituent(s) can be used with a view to making a medical diagnosis or can treat or</p>

		<p>prevent disease, including an injury, ailment or adverse condition, whether of body or mind, in humans beings.</p> <p>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.</p>
An organisation	<p>2.3 The proposed rule does not allow all medical devices to make medicinal claims, only those that contain an ancillary medicinal substance. There are devices available that do not contain an ancillary medicinal substance, but should also be able to make medicinal claims.</p> <p>For example, desensitising toothpastes can either be medical devices or medicines depending on whether their mode of action is a physical one (a medical device) or pharmacological one (medicine). The rule as proposed would not allow a toothpaste which is a medical device by virtue of its mode of action, to make a medicinal claim, even though the toothpaste relieves pain of sensitive teeth.</p>	<p>2.3 BCAP agrees. See BCAP's response to 2.2</p>
Cosmetic, Toiletry and Perfumery Association Ltd; Kao Brands;	<p>2.4 We do not agree with the proposed text of the rules and would like to see them amended to allow cosmetic products to continue to be able to make</p>	<p>2.4 BCAP agrees. See BCAP's response to 2.2</p>

secondary medicinal claims. The proposed wording of CAP rule 12.1 / BCAP rule 11.4 is not in accord with the legislation governing cosmetic products (The Cosmetics Directive 76/768/EEC) and the accumulated wisdom pertaining to the borderline situation between cosmetic products and medicinal products. The Cosmetics Directive, implemented in the UK by the Cosmetic Products (Safety) Regulations, defines cosmetic products as "... any substance or preparation intended to be placed in contact with the various external parts of the human body... with a view exclusively or mainly to cleaning them... etc." This has become accepted by competent authorities for both cosmetic and medicinal products as meaning that a cosmetic product may have a secondary function which is not a cosmetic function and yet does not disqualify that product from being a cosmetic product.

Given that European legislation includes mutual exclusivity between cosmetic and medicinal products, a product may not be a cosmetic and medicine at the same time: it can only be one or the other. Such decisions are incorporated into the Manual on the Scope of Application of the Cosmetics Directive 76/768/EEC prepared by the European Commission; this guide is based on decisions taken by member states authorities and has established precedents for cosmetic products making secondary medicinal claims yet not being re-classified as medicines on the basis of this

	<p>secondary function. We see it as important that this well-established European-level principle is not undermined by the revision of the CAP and BCAP codes.</p>	
<p>Question 61:</p> <p>i) Given BCAP’s policy consideration, do you agree that, unless prevented by law, it is not necessary to maintain the present prohibition on the use of health professionals in TV advertisements for products that have nutritional, therapeutic or prophylactic effects and in radio advertisements for treatments? If your answer is no, please explain why.</p> <p>ii) Given BCAP’s policy consideration, do you agree that rules 11.6 (relevant qualifications of health professionals in advertisements for non-medicinal products), 11.7 (financial or equivalent interest of health professional in sale of advertised product) and 11.8 (testimonials and endorsements by health professionals) should be included in the proposed BCAP Code? If your answer is no, please explain why.</p>		
<p><i>Responses received in favour of BCAP’s proposal from:</i></p> <p>Advertising Association; An organisation; IPA; KAO Brands; An organisation; Two organisations requesting confidentiality</p>	<p><i>Summaries of significant points:</i></p> <p>3.1 We agree that, unless prevented by law, it is not necessary to maintain the present prohibition of the use of health professionals in TV advertisements for products that have nutritional, therapeutic or prophylactic effects in radio advertisements for treatments. We agree to the addition of rules 11.6, 11.7 and 11.8</p>	<p><i>BCAP’s evaluation of those points and action points:</i></p>
<p>Health Food Manufacturers</p>	<p>3.2 We agree with BCAP’s proposals, but consider:</p>	<p>3.2 BCAP considers the limitations on health</p>

<p>Association</p>	<ul style="list-style-type: none"> the limitations on health professional endorsement for medicines and foods must be made clear. clarification is needed for 11.8 that such testimonials/endorsements are prohibited for medicines advertising. Medicines Regulations refer to 'recommendations by...' rather than testimonial or endorsement, although it is presumed that 'recommendations' would cover both of these. 	<p>professional endorsement for medicinal products and food is clear in the Code:</p> <p>These are not acceptable in advertisements for <u>medicinal products</u>:</p> <p>11.5.1 Presentations, by doctors, dentists, veterinary surgeons, pharmaceutical chemists, nurses, midwives and the like that imply professional advice or recommendation;</p> <p>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;</p> <p>11.5.3 references to approval of, or preference for, any relevant product, its ingredients or their use by the professions covered by 11.5.1.</p> <p>11.6 Advertisements other than those for medicinal products may feature or refer to health professionals covered by 11.5.1, if those professionals are suitably qualified in the relevant subject.</p> <p>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.</p>
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<p>Electronic Retailers Association</p>	<p>3.3 We support the proposal that health professionals can be used, in limited circumstances, to provide testimonials in advertising for health products and services. The present restrictions reflect a different</p>	<p>3.3 See above</p>

	<p>age of advertising when it was felt that using health professionals to provide testimonials could, through providing a professional endorsement, unfairly bias viewers in favour of a product. Television viewers are more sophisticated today and the limited circumstances these health professionals can be used and other rules such as those covering misleadingness should ensure proper consumer protection.</p>	
<p><i>Responses received against BCAP's proposal:</i> Archbishops Council, Church of England</p>	<p><i>Summaries of significant points:</i></p> <p>3.4 The concerns articulated clearly by BCAP in paragraph 11.30 of the consultation document outweigh the other arguments presented. Protection of the public and safeguarding the integrity of health professions ought to take priority. The current broad restrictions must remain in place.</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>3.4 BCAP will always seek to respond to new evidence as it arises, to ensure that broadcast advertising regulation remains evidence-based and targeted where needed. BCAP notes the respondents have not provided BCAP with evidence that compels it to change its proposal.</p> <p>BCAP considers its proposal to remove the prohibition on the use of health professionals in television advertisements for products that have nutritional, therapeutic or prophylactic effects and in radio advertisements for treatments, which cover a wide range of products and services, is not at the detriment of public protection or the integrity of health professionals. BCAP does not regulate health professionals; they are regulated by bodies such as the General Medical Council, the Nursing and Midwifery Council, the General</p>

Dental Council, the Royal College of Veterinary Surgeons and the like. The BCAP Code regulates advertising and should be read in conjunction with the relevant rules and codes of conduct of professional bodies. The introduction to the Medicines, Medical devices, Treatments and Health section states:

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), the European Medicines Agency (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.

BCAP considers the policy consideration outlined in its consultation document explains consumers are protected from misleading advertisements not only by the general misleading rules which will prevent advertisements for non-medicinal products claiming any greater efficacy than medicinal products, but new specific rules too:

11.6

Advertisements other than those for medicinal products may feature or refer to health professionals covered by 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.

BCAP considers the need to restrict a health professional endorsing a medicinal product is justified in light of the strict regulations surrounding such products (e.g. The Medicine (Advertising) Regulations 1994 (as amended)). The equivalent Regulations do not exist for other products that are also covered by this section.

BCAP considers its proposed three new rules to guard against the irresponsible use of health professionals in broadcast advertisements. Those ensure that the health professional is suitably qualified in the relevant field, testimonials or endorsements are genuine and supported by documentary evidence and, if relevant, his or her direct interest in the sale of the advertised product is made clear. BCAP considers its proposed new rule 1.2 'Advertisements must be prepared with a sense of responsibility to the audience and to society' (see Section 1, Compliance) will further prevent the irresponsible use of health professionals in broadcast advertisements.

BCAP considers similar restrictions on healthcare professionals are not mirrored in the present CAP

		Code and neither CAP nor the ASA have found that position to be problematic.
General Medical Council	<p>3.5 BCAP presents well founded arguments in paragraph 11.30 of the consultation document to support the current Code's prohibition on the use of health professionals to advertise products with nutritional, therapeutic or prophylactic effect (in addition to the legal prohibition on their use in advertising medicines and food). This prohibition recognises a difficulty in distinguishing between claims of 'medicinal' benefit and 'health' benefit and the possibility of the public being misled by the involvement of a health professional.</p> <p>It is difficult to see how, if the current wider restriction is removed, adequate protection would be provided by the Code's requirement that advertisements do not 'mislead' the public (section 3). The content of section 3 does not appear to bear on the public health and patient safety issues that arise in relation to products which claim to have a health benefit. In the absence of any arguments/evidence that marketers of 'health' products, or the public, are being disadvantaged by the current bar on using health professionals to advertise these products, the points made in paragraph 11.30 weigh in favour of retaining the current restriction.</p> <p>If the restriction is removed, it would seem</p>	<p>3.5 See BCAP's response to 3.4</p>

	<p>necessary for BCAP to publish advice about how marketers might avoid the problem of distinguishing between claims of health benefit and medicinal benefit. It would not be within our regulatory role, for example, to provide this sort of guidance to doctors or the marketers using their services.</p> <p>We see no reason to object to permitting the use of health professionals in advertising non-health related products, subject (as proposed) to meeting the general requirements in relation to testimonials and endorsements, declaration of any interests and not misleading the public.</p>	
<p>Proprietary Association of Great Britain</p>	<p>3.6 We disagree with BCAP's proposal. We consider BCAP's proposal would mean that companies could use health professionals to advertise cosmetics and devices, but not medicines. This will give the impression that the cosmetic or device has greater efficacy, whereas, in most cases a medicine would be more effective. There are many categories of products which include both medicines and devices, or medicines and cosmetics. These include: antiseptic creams, verruca and corn treatments, tooth pastes and mouthwashes, weight reduction products, headache products, acne treatments, eye drops, dandruff shampoos, head lice treatments and hair loss treatments etc.</p>	<p>3.6 See BCAP's response to 3.4</p> <p>BCAP considers its rules on professional endorsement, particularly rule 11.5.2, adequately explains such testimonials continue to be prohibited.</p> <p>11.5 These are not acceptable in advertisements for medicinal products:</p> <p>11.5.1 Presentations, by doctors, dentists, veterinary surgeons, pharmaceutical chemists, nurses, midwives and the like that imply professional advice or recommendation;</p> <p>11.5.2 statements that imply professional advice or</p>

	<p>For example, if an advertisement shows a midwife applying a cosmetic nappy rash cream, consumers are likely to infer that midwives recommend the advertised product. The average viewer/listener would not know that it is unacceptable for health professionals to endorse the more effective, anti-fungal nappy rash products.</p> <p>ii) 11.8 - It needs to be clear that such testimonials are prohibited for medicines advertising.</p>	<p>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 11.5.1.</p>
<p>Royal College of Midwives</p>	<p>3.7 We have strong concerns regarding the proposal to relax rules on the use of health professionals in advertisements, particularly in relation to removing the current restriction of advertisements for those products which have nutritional, therapeutic or prophylactic effects. We are particularly concerned that the presence of health professionals in such advertisements could lead to the public inferring that there are health or therapeutic benefits from a particular product, or that health professionals consider such products to be of use - even if there is no evidence or research cited that demonstrates such benefits. We consider the proposed rules do not to address the issue adequately; as public inference of benefits or health professional support could occur through the presence alone of professionals in the advertisement, without any explicit endorsement or statement of financial</p>	<p>3.7 See BCAP's response to 3.4</p>

	<p>interest. The use of health professionals in advertisements also risks undermining the trust that the public tends to have in them, especially if such trust leads to the public making decisions to purchase products which may not have any proven benefit.</p> <p>It should also be noted the relaxation of the rules could place health professionals in a position that could be difficult or in conflict with their Professional Code of Conduct. Specifically, the Nursing and Midwifery Council Code of Conduct for nurses and midwives states that, amongst other things:</p> <ul style="list-style-type: none"> ▪ <i>You must ensure any advice you give is evidence based if you are suggesting healthcare products or services</i> ▪ <i>You must not abuse your privileged position for your own ends</i> ▪ <i>You must ensure that your professional judgment is not influenced by any commercial considerations</i> ▪ <i>You must not use your professional status to promote causes that are not related to health</i> 	
The Breastfeeding Manifesto Coalition	<p>3.8 We have strong concerns regarding the proposal to relax rules on the use of health professionals in advertisements. Advertising by its very nature does not give independent and unbiased information but instead is a mode of persuasion to increase sales. Health professionals have a duty to provide evidence based information on treatment and</p>	<p>3.8 See BCAP's response to 3.4</p>

	<p>products which best meet the needs of their patients. Parents also need clear accurate information on how best to feed their child and they often rely on and trust health professionals to provide this. By using health professionals in advertisements parents may infer that the product is best for their child when there may be no evidence to suggest that this is the case. This may have a detrimental effect on a child's health and the trust parents have with health professionals. We are strongly against any further relaxation in the code which may increase the use of health professionals in advertisements of any kind.</p>	
An individual	<p>3.9 We believe it is necessary to maintain the present prohibition if it cannot be proved to medicinal standards that the product is effective.</p>	<p>3.9 See BCAP's response to 3.4</p>
Reproductive Health Matters	<p>3.10 We are opposed to the advertising of medicines and other treatments on television and radio, and in print. We have seen at firsthand the effect of such advertisements in the United States, where this has long been permitted.¹ The public are led by such advertisements to believe that they may be suffering from a condition that has not been identified and encouraged to discuss with their doctor whether they might have the</p>	<p>3.10 See BCAP's response to 3.4 It is not for BCAP to ensure that any particular product is promoted in place of another. BCAP does not regulate health professionals; they are regulated by bodies such as the General</p>

¹ Hull SC, Prasad K. Reading between the lines: direct to consumer advertising of genetic testing in the USA. Reproductive Health Matters 2001;9(18):44048.

condition and benefit from the product or treatment. We believe such advertisements encourage people to feel afraid that they are ill or under-nourished when they are not, and are therefore unethical and should be banned.

In this context, we consider it is a serious conflict of interest for any health professional to participate in selling products and treatments as described in Question 61. We believe this contributes to a culture in which health care becomes a consumer product, which in turn encourages private health care and private health insurance, all of which we oppose.

Secondly, we believe such advertisements encourage people to believe that in order to obtain certain products and treatments, they must purchase them, when in fact they may be available on the NHS if and when they are required. This could apply to products and treatments related to sexual and reproductive health, such as condoms, contraceptives, treatment for sexually transmitted infections such as herpes, vaccination against human papillomavirus, donor insemination and other assisted conception treatments. We therefore urge that any such advertisements broadcast or published in the UK should be required to state, where it is the case, that these products and treatments are available free from the NHS.

Medical Council, the Nursing and Midwifery Council, the General Dental Council, the Royal College of Veterinary Surgeons and the like. The BCAP Code regulates advertising and should be read in conjunction with the relevant rules and codes of conduct of professional bodies. The introduction to the Medicines, Medical devices, Treatments and Health section states:

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), the European Medicines Agency (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.

Question 62:

- i) Given BCAP's policy consideration, do you agree that it is necessary to maintain a rule specific to post-conception advice services and to regulate advertisements for pre-conception advice services through the general rules only?**

- ii) Given BCAP's policy consideration, do you agree that rule 11.11 (post-conception pregnancy advice services) should be included in the proposed BCAP Code? If your answer is no, please explain why.**

Ofcom and BCAP have identified some outstanding matters for further discussion on the proposal. Both parties agree that this should not delay the launch of new Broadcast Advertising Code.

Pending the conclusion of BCAP's discussions with Ofcom, the regulatory position for advertisements for post-conception advice services will remain unchanged. This means that radio advertisements will only be acceptable for family planning centres approved by a Local Health Authority, the Central Office of Information or another appropriate NHS body. On TV, advertisements for non-commercial post-conception pregnancy advice services will continue to be permitted – subject, of course, to them complying with all appropriate rules in the Code - and advertisements for commercial post-conception advice services offering individual advice on personal problems will not be acceptable.

BCAP intends to make a separate regulatory statement on this subject at the earliest opportunity.

<i>Responses received in favour of BCAP's proposal from:</i>	<i>Summaries of significant points:</i> <i>See above.</i>	<i>BCAP's evaluation of those points and action points:</i> <i>See above.</i>
<i>Responses received against BCAP's proposal:</i>	<i>Summaries of significant points:</i> <i>See above.</i>	<i>BCAP's evaluation of those points and action points:</i> <i>See above.</i>

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Question 63: Given BCAP's policy consideration, do you agree that rule 11.10 (advertisements for hypnosis-based procedures, psychiatry, psychology, psychoanalysis or psychotherapy), supported by rule 11.9 (Services including Clinics, Establishments and the like Offering Advice on, or Treatment in, Medical, Personal or other Health Matters), should be included in the proposed BCAP Code? If your answer is no, please explain why.

<p><i>Responses received in favour of BCAP's proposal from:</i></p> <p>Advertising Association; IPA; An individual; Proprietary Association of Great Britain; An organisation; An organisation</p>	<p><i>Summaries of significant points:</i></p> <p>5.1 Agree rule 11.10, supported by rule 11.9, should be included in the proposed BCAP Code.</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>5.1 BCAP agrees</p>
<p><i>Responses received against BCAP's proposal:</i></p>	<p><i>Summaries of significant points:</i></p> <p>5.2 No significant responses received.</p>	<p><i>BCAP's evaluation of those points and action points:</i></p>

Question 64:

- i) Do you think the additional requirement, that advice must be given in accordance with relevant professional codes of conduct should be extended to TV, in rule 11.13 (advertisements for services offering remote personalised advice on medical or health matters)? If your answer is no, please explain why.**
- ii) Do you think the additional requirement, that advice must be given in accordance with relevant professional codes of conduct should be extended to TV, in rule 12.3 (Advertisements for services offering remote personalised advice on health matters related to weight control or slimming) in the Weight**

Control and Slimming Section? If your answer is no, please explain why.

<i>Responses received in favour of BCAP's proposal from:</i>	<i>Summaries of significant points:</i>	<i>BCAP's evaluation of those points and action points:</i>
<p>Advertising Association; Archbishops Council, Church of England; Charity Law Association; An organisation; IPA; An organisation; An organisation</p>	<p>6.1 Agree that the additional requirement, that advice must be given in accordance with relevant professional codes of conduct should be extended to TV, in rule 11.13</p> <p>Agree that the additional requirement, that advice must be given in accordance with relevant professional codes of conduct should be extended to TV, in rule 12.3 in the Weight Control and Slimming Section.</p>	<p>6.1 BCAP agrees</p>
<p>Proprietary Association of Great Britain;</p>	<p>6.2 "Definitions" under "Weight Control and Slimming" – the reference to the Proprietary Association of Great Britain is correct, but if BCAP places it here, it should also be placed in the medicines section.</p>	<p>6.2 BCAP understands this text was included in the proposed Weight Control and Slimming section in error. BCAP has referenced other relevant Regulators in the 'Principle' of this section.</p>
<p>An organisation</p>	<p>6.3 Agrees with BCAP's proposal. Its telephone counseling is provided by fully trained members of staff. A rule to ensure TV advertisements for remote medical / health services are provided only by suitably qualified providers is vital to ensure the protection of the consumers of such services, who in the very nature of requiring such services may be particularly vulnerable.</p>	<p>6.3 BCAP agrees</p>

<p><i>Responses received against BCAP's proposal:</i></p> <p>None</p>	<p><i>Summaries of significant points:</i></p>	<p><i>BCAP's evaluation of those points and action points:</i></p>
<p>Question 65: Given BCAP's policy consideration, do you agree with BCAP's proposal to delete radio rule 3.4.28 (Sales Promotions)? If your answer is no, please explain why.</p>		
<p><i>Responses received in favour of BCAP's proposal from:</i></p> <p>Advertising Association; Bayer; IPA; Proprietary Association of Great Britain; Vifor Pharma potters; An organisation; Wyeth;</p>	<p><i>Summaries of significant points:</i></p> <p>7.1 Agree with BCAP's proposal to delete radio rule 3.4.28</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>7.1 BCAP agrees</p>
<p><i>Responses received against BCAP's proposal:</i></p> <p>Archbishops Council, Church of England;</p>	<p><i>Summaries of significant points:</i></p> <p>7.2 We disagree with BCAP's proposal. Recent efforts by pharmacies to restrict bulk buying of OTC medicines such as paracetamol have been credited with a drop in the incidence of accidental overdoses by members of the public. If the evidence referred to in 11.56 is sound, then it may</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>7.2 BCAP disagrees. The MHRA closely monitors the use of sales promotions for medicines and the Department of Health has undertaken to review the option of legislation should self-regulation prove ineffective in protecting the public. Guidelines produced by trade associations of the</p>

	<p>well be that responsible self-regulation is working. Nonetheless, deleting radio rule 3.4.28 removes an existing safeguard in the hope that it will be replaced by self-regulation backed up by other rules and practices. On balance, the interests of public safety are best served by retaining the current restrictions.</p>	<p>pharmaceutical industry such as the Proprietary Association of Great Britain (PAGB)² encourage advertisers to follow good practice and ensure a level playing field.</p> <p>BCAP has seen no evidence to date that suggests advertisements for medicines routinely include irresponsible promotions; that may suggest that self-regulation is working well in that regard. BCAP considers its proposed new rule 1.2, 'Advertisements must be prepared with a sense of responsibility to the audience and to society' (Section 1, Compliance) will further prevent irresponsible broadcast promotions for medicine. Additionally, rule 11.4 ensures advertisements are not permitted to encourage indiscriminate, unnecessary or excessive use of products covered by section 11 (Medicines, Medical Devices, Treatments and Health). Finally, radio advertisements that fall into this category <i>must</i> be centrally cleared by the RACC.</p>
<p>Question 66: Given BCAP's policy consideration, do you agree with BCAP's proposal to delete the radio rule on anti-AIDS and anti-drugs messages from BCAP's proposed Code? If your answer is no, please explain why.</p>		
<p><i>Responses received in favour of BCAP's proposal from:</i></p> <p>Advertising</p>	<p><i>Summaries of significant points:</i></p> <p>8.1</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>8.1</p>

² www.pagb.co.uk/advertising/PDFs/advertisingcode.pdf

Association; IPA; An organisation;	We agree with BCAP's proposal to delete the radio rule on anti-AIDS and anti-drugs messages from BCAP's proposed Code	BCAP agrees
Terrence Higgins Trust	<p>8.2 We support BCAP's proposal to delete the radio rule on Anti- AIDS messages. Considerable scientific and medical advances have been made in recent decades in terms of understanding HIV: how it is transmitted and its impact on the body's immune system. The availability of effective treatment now means that HIV is recognised as a long term manageable condition and as such is comparable with other illnesses such as diabetes and cancer.</p> <p>We are satisfied that the general rules that promote social responsibility and prevent advertisements from misleading or causing harm are sufficient to ensure consistency of information to the public about HIV/AIDS.</p> <p>The deletion of the radio rule is also appropriate within the context of the increasing levels of HIV recorded in the UK in recent years, with 7,734 people diagnosed in 2007 and a remaining 28% estimated to be living with HIV unknowingly³. Any measure which assists the communication of prevention and testing messages, whilst also protecting against misleading or incorrect claims, is welcome.</p>	<p>8.2 BCAP welcomes the response from the Terrence Higgins Trust.</p>

³ Health Protection Agency, *HIV in the UK: 2008 Report*, November 2008

<p><i>Responses received against BCAP's proposal:</i></p> <p>Archbishops Council, Church of England;</p>	<p><i>Summaries of significant points:</i></p> <p>8.3 We disagree with BCAP's proposal. The current restrictions ought to be maintained as anti-drugs and anti-AIDS messages need to recognise the complexity of the issues involved in these areas and they need also to reflect current medical and scientific knowledge and practice. Bodies approved by a local health authority or the Central Office of Information are likely to be able to meet these criteria while other bodies may not. Anti-drugs messages also need to be tailored to their target audiences so 'care over scheduling' continues to be relevant.</p>	<p><i>BCAP's evaluation of those points and action points:</i></p> <p>8.3 BCAP considers those radio rules were likely reflect the need, at the time the rule was published, to ensure a consistency of information to the public about HIV/AIDS in particular. The Television Code does not include an equivalent rule.</p> <p>On balance, BCAP considers those radio rules are not necessary given BCAP's proposal to maintain rules that prevent advertisements from misleading, causing harm, serious or widespread offence or unnecessary distress and scheduling rules that ensure that those advertisements are appropriately and sensitively scheduled. BCAP considers its proposed new rule 1.2, Advertisements must be prepared with a sense of responsibility to the audience and to society' (see Section 1, Compliance) will further prevent irresponsible broadcast advertisements that contain anti-drugs and anti-AIDS messages.</p>
<p>Question 67:</p> <p>i) Taking into account BCAP's general policy objectives, do you agree that BCAP's rules, included in the proposed Medicines, Medical Devices, Treatments and Health Section are necessary and easily understandable? If your answer is no, please explain why.</p>		

- ii) On consideration of the mapping document in Annex 2, can you identify any changes from the present to the proposed Medicines, Medical Devices, Treatments and Health rules that are likely to amount to a significant change in advertising policy and practice and are not reflected here and that should be retained or otherwise be given dedicated consideration?
- iii) Do you have other comments on this section?

<i>Responses received from:</i>	<i>Summaries of significant points:</i>	<i>BCAP's evaluation of those points and action points:</i>
Advertising Association; Charity Law Association; IPA; An organisation; An organisation	<p>9.1 Agree that BCAP's rules, included in the proposed Medicines, Medical Devices, Treatments and Health Section are necessary and easily understandable. Respondents cannot identify any changes from the present to the proposed Medicines, Medical Devices, Treatments and Health rules that are likely to amount to a significant change in advertising policy and practice and are not reflected here and that should be retained or otherwise be given dedicated consideration.</p>	
Department of Health	<p>9.2 The Medicines and Healthcare Products Regulatory Authority (MHRA) has reviewed the sections on medicines and medicinal products and has no significant policy concerns with the proposals. Minor points of detail relating to interpretation of medicines advertising legislation will be dealt with in a direct response.</p>	

<p>British Retail Consortium Consumer Policy Group</p>	<p>9.3 Much of the contents of this section are superfluous. Medicines and health products are highly regulated and the law is well known. There is no need for additional rules in this tightly controlled area.</p>	<p>9.3 BCAP considers the Code should reflect the law, particularly advertising specific provisions that directly affect broadcast advertisements. Advertising stakeholders are reminded the Code is not a replacement for relevant legislation.</p>
<p>Health Food Manufacturers Association</p>	<p>9.4 The final sentence of the Principle could confuse. Therapeutic or prophylactic effects are generally considered to be ‘medicinal’ rather than ‘health’ claims.</p> <p>Further clarity is needed in rule 11.27 Medicines Regulations prohibit <i>‘recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products’</i>.</p> <p>No distinction is made in the Regulations between testimonials, endorsements, etc. by celebrities.</p>	<p>9.4 Principle 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. <u>Health claims may, for example, relate to the therapeutic or prophylactic effects of products, including toiletries and cosmetics.</u></p> <p>BCAP considers therapeutic or prophylactic effects aren’t <u>limited</u> to medicinal products. This section covers products other than medicines.</p> <p>Testimonials or endorsements would be considered as recommendations. BCAP agrees recommendation is preferable in this rule: 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</p>

	Perhaps 11.27 should more correctly refer to 'recommendation' rather than just to 'testimonials'.	as singular and would prohibit, for example, recommendations by medical charities, patient groups and health or sport organisations.
Proprietary Association of Great Britain	<p>9.5The "Principle" on page 241 of BCAP Consultation Document and Annex 1 states "Health claims may, for example, relate to the therapeutic or prophylactic effects of products, including toiletries and cosmetics." Claims or therapeutic or prophylactic effects are almost always medicinal claims rather than health claims.</p>	<p>9.5 (See BCAPs response to 9.4)</p>
	<p>11.3, page 242. It would be very helpful to include the same qualifier as has been included in the corresponding rule (12.2) of the CAP Code. The qualifier in the CAP Code is:</p> <p>12.11 Medicines must have a license from the MHRA before they are marketed. Marketing communications for medicines must conform with the license and the product's summary of product characteristics. For the avoidance of doubt, by conforming with the product's indicated use, a marketing communication would not breach 12.2."</p>	<p>BCAP agrees the additional text clarifies the intention of the rule.</p> <p>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 11.9) That does not prevent advertising for spectacles, contact lenses or hearing aids.</p> <p>11.19 Medicines must have a licence from the MHRA</p>

	<p>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. <u>For the avoidance of doubt, by conforming with the product’s indicated use, an advertisement would not breach 11.3.</u></p>
<p>Rule 11.17 - Unsure as to why jingles are prohibited if the claim is appropriate for the product?</p>	<p>BCAP agrees. BCAP considers substantiated jingles are acceptable in advertisements:</p> <p>11.17 Jingles may be used. Those that incorporate a medical or health claim must be substantiated.</p>
<p>Rule 11.20 - Suggest adding ‘and any other information specifically required by the by the product’s Summary of Product Characteristics’ to the end of this list.</p>	<p>BCAP considers the proposed rule reflects the law. Additional wording as required by the product is not for the Code to determine.</p>
<p>Rule 11.27 –The regulation states that celebrity endorsement is not prohibited, only testimonials by a person well-known in public life etc.</p>	<p>BCAP considers a celebrity would be considered a person well-known in public life and therefore under the Medicine (Advertising) Regulations, could encourage the consumption of medicinal products. See also BCAP’s evaluation in 9.4.</p>

	<p>Rule 11.34 - We suggest deleting this rule. It is an example of an advertiser not complying with the therapeutic indication on the SPC. It is already covered by 11.19.</p>	<p>BCAP considers the rule on analgesics is necessary given the prevalence of advertisements for such products. This is an existing rule in the BCAP TV and Radio Codes.</p>
<p>Radio Advertising Association</p>	<p>9.6 We suggest deletion of the word “BCAP” as in the sentence “The ASA or BCAP may seek a medical opinion...” if this requirement is confined to ASA’s complaint investigation powers;</p> <p>Rule 11.2: suggest “or their clearance bodies” should be added after the word “broadcasters” and also the phrase “and/or” in place of “and” in the requirement for “generally accepted scientific advice and independent expert advice” (i.e. both criteria are not always needed simultaneously);</p>	<p>9.6 This is not limited to ASA complaint investigations. The BCAP compliance and monitoring team will begin a challenge under BCAP’s remit. If a case proceeds to a formal investigation, that investigation is carried out under ASA’s remit. See ‘Broadcast complaint handling procedures’ : http://asa.org.uk/Complaints-and-ASA-action/Dealing-with-complaints/Complaints-and-investigations-process.aspx</p> <p>BCAP considers the Code applies to broadcasters. The ‘Background’ to the Compliance section states:</p> <p>Broadcasters must ensure that previously approved copy is not re-run for subsequent campaigns without periodic checks to ensure that all claims are still accurate. For radio, copy originally cleared by the RACC that is over six months old, will need to be re-submitted for consideration by the RACC and assigned a new clearance number. <u>Broadcasters or their respective clearance body must independently</u></p>

	<p>There is unnecessary duplication between rule 11.9 and Section 26 and suggests that the requirements are amalgamated into one single rule.</p>	<p><u>assess evidence submitted in support of an advertisement and any advice they have commissioned. Substantiation of factual claims made by advertisers and other supporting evidence must be held by the broadcaster or the relevant clearance body.</u></p> <p>BCAP considers this adequate. The need to hold evidence prior to broadcast is not limited to this section.</p> <p>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 members' 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.</p> <p>Services Offering Individual Advice on Consumer or Personal Problems 26.2 Services offering individual advice on consumer or personal problems may be advertised only if</p>
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