CAP Medicines Consultation

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

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Legal, decent, honest and truthful

Contents

1. Executive Summary

The Committee of Advertising Practice (CAP), author of the UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code) is consulting on proposals to amend the *Medicines, medical devices, health-related products and beauty products* section of the CAP Code ("Section 12").

Primarily, the consultation relates to the need for several amendments in response to the enactment of the Human Medicines Regulations 2012 (HMRs), which consolidate the various pieces of UK medicines legislation into one statutory instrument. The HMRs do not represent a significant change in medicines advertising policy. Nevertheless, CAP is keen to ensure that the Code is kept up to date.

CAP's objectives are to:

- Update references to and provide greater clarity on the legislation underpinning Section 12;
- Amend rules to follow the wording and approach of the HMRs more closely; and
- Introduce, where necessary, new rules or amendments to existing rules to ensure that the Code is in line with the relevant legislative frameworks.

The consultation will close at **5pm on Friday 25 October 2013**. For more information on the next steps see section 6 and, for full details of how to respond to the consultation, please see Annex 1.

2. Introduction to CAP and the ASA

2.1 The Committee of Advertising Practice

CAP is the self-regulatory body that creates, revises and enforces the CAP Code. The CAP Code covers non-broadcast marketing communications, which include advertisements placed in traditional and new media, sales promotions, direct marketing communications and marketing communications on marketers' own websites. The marketer has primary responsibility for complying with the CAP Code and compliance is not voluntary. Parties that do not comply with the CAP Code could be subject to adverse publicity, resulting from adjudication by the Advertising Standards Authority (ASA), or further sanctions including the denial of media space.

CAP's members include organisations that represent the advertising, sales promotion and direct marketing and media businesses. Through their membership of CAP member organisations, or through contractual agreements with media publishers and carriers, those businesses agree to comply with the Code so that marketing communications are legal decent, honest and truthful, and consumer confidence is maintained.

By practising self-regulation, the marketing community ensures the integrity of advertising, promotions and direct marketing. The value of self-regulation as an alternative to statutory control is recognised in EC Directives, including on misleading advertising (Directive 2005/29/EC). Self-regulation is accepted by the Department for Business, Innovation and Skills and the Courts as a first line of control in protecting consumers and the industry.

Information about CAP is available at www.cap.org.uk, which includes a copy of the CAP Code.

2.2 The Advertising Standards Authority

The ASA is the independent body responsible for administering the CAP Code and the UK Code of Broadcast Advertising (the BCAP 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 marketing communication must be withdrawn or amended. CAP conducts compliance, monitoring and research to enforce the ASA Council's decisions.

The ASA's work in regulating non-broadcast marketing communications 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. Policy Background

3.1 General policy objectives

CAP's general policy objective is to set standards to ensure that all non-broadcast marketing communications covered by the CAP Code are legal, decent, honest and truthful and prepared with a due sense of social and professional responsibility.

CAP intends the CAP Code to be based on the enduring principles that marketing communications should be responsible, respect the principles of fair competition generally accepted in business and should not mislead, harm or offend. CAP is keen to maintain an environment in which responsible non-broadcast advertising can flourish.

CAP 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.

3.2 The CAP Code and medicines advertising

CAP recognises the importance of consumers receiving accurate and responsible information through advertising for medicines and health related products and services.

Section 12 of the CAP Code covers marketing communications 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 12 includes rules derived from statutory frameworks, such as those governing medicines and medical devices, alongside self-regulatory principles covering advertising generally. This allows the CAP Code to apply consistent standards across the various sectors covered by Section 12, whilst conforming to specific legal requirements for certain products and services.

The most prominent statutory framework incorporated into Section 12 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).

3.3 Consolidation of UK medicines law

The present regulations governing the advertising of medicines for human use, the HMRs, came into force in August 2012.

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.

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.

4. CAP's Decision to Consult

4.1 Concerns over consistency between the Code and HMRs

CAP conducted an analysis of the final draft of the consolidation of UK medicines regulations against the Code to assess the need for regulatory change and/or technical updates to ensure that Section 12 properly reflects the legislative framework.

Beyond the immediate need for technical updates, for instance, to update references to the legislative framework, the analysis revealed several inconsistencies between the HMRs and the Code. CAP believes the issues identified are related to the way in which the Code has been updated incrementally over time since the first European-wide framework for medicines regulation was introduced in the 1990s.

CAP considers that to implement the changes proposed in section 5 below would not constitute a significant change in advertising policy or practice. Nevertheless, if there are inconsistencies between certain rules and the statutory framework upon which they are based, there is a danger of confusion among Code users and the potential for the Code and decisions made by the ASA to be subject to challenge.

4.2 CAP's decision to consider amending the Code

CAP considers that the implementation of the HMRs provides a timely opportunity for it to make necessary changes to secure the Code against the risks noted above and to improve clarity for the benefit of Code users. It is also an opportunity to consider the need for any similar amendments related to other relevant statutory frameworks with similar objectives in mind; in particular, CAP is concerned about how Section 12 explains its application to veterinary medicinal products.

In coming to its decision, CAP 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 CAP consultation on the proposals outlined in section 5 below.

4.3 Policy objectives

In response to the potential problems identified, CAP considers that it is desirable to amend the Code with the objectives of:

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

4.4 Using this consultation document

The proposed amendments to the Code are set out in section 5 below. Each is identified by a letter (Amendments A-I) and presented broadly in order of appearance in the Code.

The amendments are suffixed with "(CAP)" to ensure that there is no confusion with the Broadcast Committee of Advertising Practice (BCAP) consultation on the medicines section of the BCAP Code, which covers some of the same issues as CAP'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 to only one consultation.

For each proposed amendment, CAP has outlined the issue or issues that have given it cause to consider amending the Code, along with the proposed amendment(s) to the Code. Respondents should also have regard to the legislative framework outlined in section 3 and CAP's wider objectives and consideration outlined above.

The wording of the proposed amendments is contained in the boxes at the end of each Amendment, together with the consultation questions.

- Rules and text within Section 12 that are affected by the proposed amendments are included in the boxes at the end of each Amendment.
- The proposed changes are shown in darker text; deleted wording is struck-through.
- Wording that is unaffected is shown in lighter text.
- Cross-references between different Amendments are denoted by, for instance, "**[see Amendment F (CAP)]**".
- A full marked-up version of the amended Section 12 is included in Annex 2.

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

4.5 Setting expectations

CAP is conducting this consultation in order to address specific policy issues. While it welcomes a broad range of comments from any party wishing to respond, CAP does not consider that this process should serve as an opportunity for a general review of Section 12.

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

5. Proposed Amendments to the Code

5.1 Amendment A (CAP) – Addition of a "Scope" sub-section

It is CAP's wider objective to ensure that the Code is easily understood. It is therefore important for the Code to include necessary background information to make clear the context in which the rules should be interpreted. This consideration is particularly important in a Code section that covers a broad variety of products and services, which are regulated by a variety of statutory frameworks.

CAP is concerned that the relationship to the various statutory frameworks could be made clearer and considers that the introduction of the HMRs provides a timely opportunity to consider how that might be achieved. However, CAP's analysis of the matter has also identified three instances, in particular, where interpretive problems might arise for the ASA and Code users:

a) The HMRs include exemptions to some advertising-related provisions for certain products. For example, Regulation 292 (Exceptions for approved vaccination campaigns) exempts vaccination campaigns approved by ministers from several requirements of the HMRs that are reflected by rules in the Code. The exemptions are only likely to be relevant in a very narrow set of circumstances. However, the absence of sufficient explanation of how the rules should be interpreted with regard to the relevant underlying legislation might lead to instances where rules derived from HMRs are employed when an exemption applies.

b) The definition of an "advertisement" in the HMRs goes significantly further than the application of the CAP Code as outlined in the "Scope of the Code". Regulation 7 (Advertising related to medicinal products) defines an "advertisement" as including "anything designed to promote the prescription, supply, sale or use of that product." This includes a variety of activities not covered by the Code, such as door-to-door canvassing and sponsorship of events. The Code's approach is to apply relevant HMRs-derived rules to content within the scope of the Code; practices outside this are regulated by the MHRA and other regulatory bodies in the medicines sector. A further problem arises for the application of the HMRs-derived rules in Section 12 because the HMRs also exclude certain types of content that are within the scope of the CAP Code; of principal concern are marketing communications appearing on websites.

   In March 2011, CAP extended its remit to cover marketing communications on marketers' own websites and in other third party space under their control. At the time, it undertook an assessment of potential conflicts between the Code and pre-existing statutory regimes covering the online space. It concluded that, where the HMRs-derived rules in Section 12 were concerned, code users should have regard to the definition of an "advertisement" adopted in the legislative framework (then, the Medicines (Advertising) Regulations 1994) as well as the information given in "Scope of the Code". The HMRs make an exemption for "reference material and announcements of a factual and informative nature, including trade catalogues, and price lists". In practice, this is interpreted by the MHRA to allow marketers, such as online pharmacies, to include information about prescription-only medicines (POMs) that might be

prescribed as part of a consultation service offered via the website. Prior to the remit extension, the ASA interpreted the rule prohibiting the advertisement of POMs (rule 12.12) as preventing virtually any reference to a POM in a marketing communication.

To resolve this issue, CAP advised the ASA to cite to the introductory text of the "Medicines" sub-section of Section 12, which gives a basic outline of the legislative framework, in order to justify making the distinction over the application of the HMRs-derived rules necessitated by the legislative framework's differing position on the definition of an "advertisement". However, that text is limited and potentially unclear; it includes no explicit reference to the rules being read in conjunction with the underlying legislation. Furthermore, CAP is concerned that, having cited the legislative framework (specifically, Regulation 7) to exclude content that might otherwise be in the Code's remit, there is insufficient clarification that other activities listed in Regulation 7 are still excluded from the CAP Code's remit. Without proper clarification, it is unclear what aspects of the HMR's definition of an "advertisement" the Code addresses and which HMRs-derived rules consequently apply.

c) Where relevant, the rules of Section 12 apply to veterinary medicines. As some of the rules serve a dual purpose, there is potential uncertainty as to their application and the underlying statutory framework(s) to which marketers should have regard when interpreting the rules. CAP is concerned that the Code only refers to veterinary medicines in the text of rule 12.1.

To resolve these issues, CAP proposes the addition of a "Scope" sub-section. The new sub-section is intended to make clear to Code users that the rules should be read in accordance with the HMRs, as well as other statutory regimes. Specifically, it is intended to give the ASA an appropriate degree of flexibility to ensure that it can enforce Section 12 in line with the legislative framework. Furthermore, CAP considers that it is appropriate to move the existing reference to the application of relevant rules in Section 12 to advertisements for veterinary products from rule 12.1 to the new "Scope" section and add clarification and a link to external guidance on the extent of the application of Section 12 to veterinary products.

Proposed Wording	**Scope** The rules in the first part of this section apply to all marketing communications for medicines, medical devices, treatments, health-related products and beauty products. The rules in subsequent parts apply to marketing communications for specific products and/or services. If relevant, the rules in this section also apply to claims for products for animals. As they apply to medicinal products for human use, the rules should be read in conjunction with the relevant sections of the Human Medicines Regulations 2012. This is particularly the case in relation to the definition of a marketing communication. Rules in this section apply to marketing communications, as set out in the Scope of the Code, that are also subject to the Regulations. Other activities defined as advertising in the Human Medicines Regulations 2012 that are outside the remit of the Code, specifically those listed in Regulation 7(2), are not covered by this section. As they apply to medicines for veterinary use, the rules should be read in conjunction with the Veterinary Medicines Regulations. For more information please see Veterinary medicines Guidance Note 4, Controls on Advertising,

	www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

Question 1	**Do you agree with the proposal to add a "Scope" sub-section to Section 12? If not, please explain why.**
Question 2	**Do you agree to the wording of the proposed "Scope" sub-section? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

5.2 Amendment B (CAP) – 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.

CAP considers that the various references to licensing requirements are inconsistent or incomplete:

- rule 12.1 does not make clear that the EMA grants licences on behalf of the European Commission;
- rule 12.11 refers only to the MHRA's role in granting medicines licences valid in the UK; and
- the role of the VMD is not made clear at all in Section 12.

To resolve these issues, CAP proposes the following amendments to avoid any potential ambiguity over which bodies are responsible for granting medicines licences valid in the UK and necessary to allow a product to be advertised.

CAP also proposes to amend all relevant references, principally in the "Background" sub-section of Section 12 and rule 12.1, to ensure the EMA initialism and URL are correct following the change in acronym from "EMEA" to "EMA".

Proposed Wording	**Background** The rules in this section are designed to ensure that marketing communications for medicines, medical devices, treatments, health-related products and beauty products receive the necessary high level of scrutiny. The rules apply to marketing communications and not the products, which are regulated by health regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), www.mhra.gov.uk, the European Medicines Agency ~~(EMEA)~~ (EMA), ~~www.emea.europa.eu~~ www.ema.europa.eu, the Veterinary Medicines Directorate (VMD) and the Department of Health, www.dh.gov.uk. Marketing communications for those products must comply with the rules and professional codes of conduct of relevant professional bodies […] 12.1 Objective claims must be backed by evidence, if relevant consisting of trials conducted on people. ~~If relevant, the rules in this section apply to claims for products for animals~~. **[see Amendment A (CAP) above]** Substantiation will be assessed on the basis of the available scientific knowledge. Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA 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. […] 12.11 Medicines must have a licence from the MHRA, VMD or under the auspices of the EMA before they are marketed. Marketing communications for medicines must conform with the licence 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 rule 12.2. Marketing communications must not suggest that a product is "special" or "different" because it has been granted a licence by the MHRA, VMD or under the auspices of the

	EMA.

Question 3	**Do you agree with the proposal to amend the "Background" sub-section and rules 12.1 and 12.11 of Section 12? If not, please explain why.**
Question 4	**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.**

5.3 Amendment C (CAP) – Remote treatment and medicinal products

Regulation 286 (Material relating to diagnosis) of the HMRs states:

> (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.

In the early 1990s, CAP removed a broad rule prohibiting advertisements for services offering to prescribe or treat remotely. Such services may now be advertised, but the decision to remove the blanket prohibition inadvertently left the Code without a rule mirroring the requirement of Regulation 286(2) and its predecessor in the Medicines (Advertising) Regulations 1994.

The wording of the Medicines (Advertising) Regulations 1994 did not include a reference to electronic communications networks. Arguably, this justified the omission of an equivalent rule from the Code on the grounds that such a provision was very unlikely to be used in relation to services provided by traditional means of communication. However, the updated wording of the HMRs, in conjunction with the growth of mainstream website-based services offering remote treatment that are within the Code's extended remit, persuades CAP of the need to introduce a rule mirroring Regulation 286(2).

To resolve this issue, CAP proposes a new rule to mirror Regulation 286(2) and bring the Code into line with the requirements of the law.

Proposed Wording	12.2.1	Marketing communications for medicinal products must not offer to provide a diagnosis or suggest a treatment by correspondence, for instance, by post, by e-mail or other means of an electronic communications network.

Question 5	**Do you agree with the proposal to add a new rule, 12.2.1, to Section 12? If not, please explain why.**
Question 6	**Do you agree to the wording of the proposed rule? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

5.4 Amendment D (CAP) – Medicinal Products and Side-effects

Regulation 287 (Material about effects of medicinal product) states:

> (1) A person may not publish an advertisement relating to a medicinal product that suggests that the effects of taking the medicinal product—
>
> (a) are guaranteed;
>
> (b) are better than or equivalent to those of another identifiable treatment or medicinal product; or
>
> (c) are not accompanied by any adverse reaction.

CAP Code rule 12.9, which is intended to cover this provision, applies to all products and services covered by Section 12. The portion of the rule relevant to Regulation 287 states:

> Marketers … must hold proof before suggesting their product or therapy is guaranteed to work, absolutely safe or without side-effects.

CAP is concerned that, contrary to Regulation 287(1) (a) and (c), rule 12.9 does not prohibit claims that a medicinal product has no side effects or that its effects are guaranteed, but merely asks marketers to provide supporting evidence for such a claim. The "Medicines" sub-section of Section 12 does not include a specific rule for medicinal products prohibiting this type of claim, although rule 12.19 does incorporate part of Regulation 287(1), provision (b).

To resolve these issues, CAP proposes to amend rule 12.19 to incorporate Regulation 287(1) (a) and (c). Furthermore, CAP proposes an amendment to 12.9 making it subject to an amended rule 12.19. This will serve to differentiate between the status of medicinal products and other products or therapies covered by this Section 12.

Proposed Wording	12.9	Marketers must not consumers to use a product to excess and must hold proof before suggesting their product or therapy is guaranteed to work, absolutely safe or without side-effects (subject to rule 12.19). […]
	12.19	Marketing communications for a medicine may not claim that its effects are guaranteed, that it is absolutely safe or without side-effects or as good as or better than those of another identifiable product.

Question 7	**Do you agree with the proposal to amend rules 12.9 and 12.19 of Section 12? 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.**

5.5 Amendment E (CAP) – References to the Legislative Framework

CAP considers that it is important for the Code to include necessary background information to make clear the context in which the rules should be interpreted. The "Medicines" sub-section is intended to do this; however, the introduction of HMRs renders some of the background information out of date. Also, further to the point made in 5.1 c) above, there is no outline of the role of the VMD in relation to the legal framework governing veterinary medicines.

To resolve these issues, CAP proposes to amend the introductory text of the "Medicines" sub-section to reflect the introduction of the HMRs and to provide clarity on the veterinary medicines framework. CAP also proposes an update to reflect the change in responsibility for regulating healthcare services from the Healthcare Commission to the Care Quality Commission (CQC).

Proposed Wording	**Medicines** Title VIII of European Directive 2001/83/EC (as amended) concerns "The Advertising of Medicinal Products for Human Use" and has been implemented in the UK by the Human Medicines Regulations 2012. Advertisements for products subject to licensing under the Human Medicines Regulations 2012 must comply with the requirements of the Regulations and any conditions contained in the marketing authorisation, certificate, licence or traditional herbal registration for the advertised product. For more information on medicinal products and medical devices, go to: www.mhra.gov.uk. For more information on medical treatments, go to: ~~www.healthcarecommission.org.uk~~ www.cqc.org.uk. Advertisements for products subject to authorisation under the Veterinary Medicines Regulations must comply with the requirements of the Regulations and any conditions contained in the marketing authorisation, certificate or registration for the advertised product. For more information please see Veterinary medicines Guidance Note 4 Controls on advertising (http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx)

Question 9	**Do you agree with the proposal to amend the introductory text of the "Medicines" sub-section of Section 12? If not, please explain why.**
Question 10	**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.**

5.6 Amendment F (CAP) – Effects of a Medicinal Product

Regulation 287 (Material about effects of medicinal product) states:

> (2) A person may not publish an advertisement relating to a medicinal product that uses in terms that are misleading or likely to cause alarm pictorial representations of—
>
> (a) changes in the human body caused by disease or injury; or
>
> (b) the action of the medicinal product on the human body.

CAP is concerned that the wording of its equivalent Code rule does not narrow the focus of the provision to "pictorial representations" and may therefore result in the Code going beyond the HMRs. Code rule 12.14, states:

> Marketers must not use fear or anxiety to promote a medicine or a recovery from illness, and must not suggest that using or avoiding a product can affect normal health.

It is not CAP's intention for the rule to exceed the requirements of HMRs and CAP does not consider that there are grounds for doing so, given that the Code includes general harm provisions that address instances of irresponsible advertising or advertising that unduly appeals to fear.

To resolve this issue, CAP proposes to better reflect the wording of Regulation 287. However, owing to the issues outlined in Amendments G and H below, it proposes to delete rule 12.14 entirely and replace it with a new, restructured rule reflecting several other provisions from Regulations 286 and 287. For the purposes of Amendment F, CAP proposes to replace rule 12.14 with rules 12.14.1 and 12.14.3, incorporating revised wording in 12.14.1 to better reflect Regulation 287(2).

Proposed Wording	12.14 ~~Marketers must not use fear or anxiety to promote a medicine or a recovery from illness, and must not suggest that using or avoiding a product can affect normal health.~~ Marketing communications for medicinal products must not: 12.14.1 use, in improper, alarming or misleading terms, images of changes in the human body caused by disease, injury or a medicinal product. 12.14.2 refer, in improper, alarming or misleading terms, to claims of recovery. **[See Amendment G Below]** 12.14.3 suggest that using or avoiding a product can affect normal health. 12.14.4 present a description or detailed representation of a case history that might lead to erroneous self-diagnosis. **[See Amendment H Below]**

Question 11	**Do you agree with the proposal to replace the relevant portions of rule 12.14 with rules 12.14.1 and 12.14.3? If not, please explain why.**
Question 12	**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.**

5.7 Amendment G (CAP) – Material Relating to Diagnosis

Regulation 287 (Material relating to diagnosis) states:

> (3) A person may not publish an advertisement relating to a medicinal product that refers in terms that are misleading or likely to cause alarm to claims of recovery.

CAP Code rule 12.14, which serves to cover this provision, states:

> Marketers must not use fear or anxiety to promote a medicine or a recovery from illness.

The meaning of the wording "to promote … a recovery from illness" is, in CAP's view, potentially unclear and is at odds with Regulation 287(3), which is focused on advertisements that refer to "claims of recovery".

To resolve this issue (in conjunction with Amendment F above), CAP proposes to replace the relevant wording of the current rule with 12.14.2, which will be incorporated into the restructured 12.14.

Proposed Wording	12.14 ~~Marketers must not use fear or anxiety to promote a medicine or a recovery from illness, and must not suggest that using or avoiding a product can affect normal health.~~ Marketing communications for medicinal products must not: 12.14.1 use, in improper, alarming or misleading terms, images of changes in the human body caused by disease, injury or a medicinal product. **[See Amendment F above]** 12.14.2 refer, in improper, alarming or misleading terms, to claims of recovery. 12.14.3 suggest that using or avoiding a product can affect normal health. **[See Amendment F above]** 12.14.4 present a description or detailed representation of a case history that might lead to erroneous self-diagnosis. **[See Amendment H Below]**

Question 13	**Do you agree with the proposal to replace the relevant portion of rule 12.14 with rule 12.14.2? If not, please explain why.**
Question 14	**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.**

5.8 Amendment H (CAP) – Self-Diagnosis

Regulation 286 (Material relating to diagnosis) states:

> (3) A person may not publish an advertisement relating to a medicinal product that might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.

Rule 12.5, which is intended to cover this provision, refers only to instances where an invitation to diagnose is made, as opposed to the wider approach taken in the HMRs. It states:

> Marketers inviting consumers to diagnose their minor ailments must not make claims that might lead to a mistaken diagnosis.

Rule 12.5 is a general rule applying to all products and therapies covered by Section 12, not merely medicinal products. CAP is concerned that a marketing communication for a medicinal product, which does not feature an invitation to self-diagnose, could potentially lead to an erroneous self-diagnosis, in the manner envisaged and prohibited by Regulation 286, whilst being in compliance with rule 12.5.

CAP considers it important to differentiate between the requirements for medicinal products and those for other products or services. However, it does not consider that this is the appropriate juncture to explore whether the approach mandated by Regulation 286 should be applied to marketing communications for products and services covered by Section 12 other than medicinal products.

To resolve this issue, CAP proposes the addition of a new rule, 12.14.4, which will be incorporated into the restructured 12.14.

Proposed Wording	12.14 ~~Marketers must not use fear or anxiety to promote a medicine or a recovery from illness, and must not suggest that using or avoiding a product can affect normal health.~~ Marketing communications for medicinal products must not: 12.14.1 use, in improper, alarming or misleading terms, images of changes in the human body caused by disease, injury or a medicinal product. **[See Amendment F above]** 12.14.2 refer, in improper, alarming or misleading terms, to claims of recovery. **[See Amendment G above]** 12.14.3 suggest that using or avoiding a product can affect normal health. **[See Amendment F above]** 12.14.4 present a description or detailed representation of a case history that might lead to erroneous self-diagnosis.

Question 15	**Do you agree with the proposal to add a new rule, 12.14.4, to Section 12? If not, please explain why.**
Question 16	**Do you agree to the wording of the proposed rule? If not, please explain why and include any alternative wording that you consider to be more appropriate.**

5.9 Amendment I (CAP) – Traditional herbal medicinal products

Regulation 302 (Advertisements for traditional herbal medicinal products) states:

> A person may not publish an advertisement relating to a herbal medicinal product to which a traditional herbal registration relates unless it contains—
>
> (a) the words “Traditional herbal medicinal product for use in”; followed by .
>
> (b) a statement of one or more therapeutic indications for the product consistent with the terms of the registration; followed by .
>
> (c) the words “exclusively based on long standing use”.

Rule 12.13, concerning information required in marketing communications for medicinal products, traditional herbal medicinal products and homeopathic medicinal products, refers to the requirement for mandatory information. However, Rule 12.21 does not, referring only to the requirement in Regulation 302(b). It states:

> Marketers of traditional herbal medicines may advertise for the indications listed in the product’s summary of product characteristics. Marketing communications for products that hold a Traditional Herbal Medicines Registration must not imply that registration is based upon clinical trials.

Moreover, the rule 12.21 does not make sufficiently clear that the wording requirements are mandatory. CAP is concerned that the position established by rules 12.13 and 12.21 in relation to traditional herbal medicinal products is potentially ambiguous.

To resolve this issue, CAP proposes that rule 12.21 should also direct marketers to the MHRA Blue Guide for details of the required information.

Proposed Wording	12.21 Marketers of traditional herbal medicines may advertise for the indications listed in the product’s summary of product characteristics and must include mandatory information, which can be found in the MHRA’s “The Blue Guide: Advertising and Promotion of Medicines in the UK” at www.mhra.gov.uk. Marketing communications for products that hold a Traditional Herbal Medicines Registration must not imply that registration is based upon clinical trials.

Question 17	**Do you agree with the proposal to amend rule 12.21 of Section 12? If not, please explain why.**
Question 18	**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. Next Steps

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

Given the sector-specific nature of this consultation, CAP 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 CAP'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**.
- CAP 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 CAP website when the outcome of the consultation is announced.

7. Annex 1: Responding to this Consultation

7.1 How to respond

CAP 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:

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

7.2 Confidentiality

CAP considers that everyone who is interested in the consultation should see the consultation responses. In its evaluation document, CAP 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.

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

Medicines, medical devices, health-related products and beauty products

Background

The rules in this section are designed to ensure that marketing communications for medicines, medical devices, treatments, health-related products and beauty products receive the necessary high level of scrutiny. The rules apply to marketing communications and not the products, which are regulated by health regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA), www.mhra.gov.uk, the European Medicines Agency ~~(EMEA)~~ (EMA), ~~www.emea.europa.eu~~ www.ema.europa.eu, the Veterinary Medicines Directorate (VMD) and the Department of Health, www.dh.gov.uk. Marketing communications for those products must comply with the rules and professional codes of conduct of relevant professional bodies

Amendment B (CAP)

Scope

The rules in the first part of this section apply to all marketing communications for medicines, medical devices, treatments, health-related products and beauty products. The rules in subsequent parts apply to marketing communications for specific products and/or services. If relevant, the rules in this section also apply to claims for products for animals.

As they apply to medicinal products for human use, the rules should be read in conjunction with the relevant sections of the Human Medicines Regulations 2012. This is particularly the case in relation to the definition of a marketing communication. Rules in this section apply to marketing communications, as set out in the Scope of the Code, that are also subject to the Regulations. Other activities defined as advertising in the Human Medicines Regulations 2012 that are outside the remit of the Code, specifically those listed in Regulation 7(2), are not covered by this section.

Amendment A (CAP)

As they apply to medicines for veterinary use, the rules should be read in conjunction with the Veterinary Medicines Regulations. For more information please see Veterinary medicines Guidance Note 4, Controls on Advertising, www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

Definition

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

For more information, see CAP Help Notes, especially those on: Substantiation for Health, Beauty and Slimming Claims; Health, Beauty and Slimming Advertisements that Refer to Medical Conditions; Cosmetic Surgery Marketing and Use of Experts by the ASA and CAP.

Rules

12.1 Objective claims must be backed by evidence, if relevant consisting of trials conducted on people. ~~If relevant, the rules in this section apply to claims for products for animals~~. Substantiation will be assessed on the basis of the available scientific knowledge. Medicinal or medical claims and indications may be made for a medicinal product that is licensed by the MHRA or under

Amendment A (CAP)

Amendment B (CAP) →

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.

12.2 Marketers 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. Accurate and responsible general information about such conditions may, however, be offered. (See rule 12.11.)

Health professionals will be deemed suitably qualified only if they 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.

Amendment C (CAP) →

12.2.1 Marketing communications for medicinal products must not offer to provide a diagnosis or suggest a treatment by correspondence, for instance, by post, by e-mail or other means of an electronic communications network.

12.3 Marketers offering individual treatments, especially those that are physically invasive, may be asked by the media and the ASA to provide full details together with information about those who supervise and administer them. Practitioners must have relevant and recognised qualifications. Marketers should encourage consumers to take independent medical advice before committing themselves to significant treatments, including those that are physically invasive.

12.4 Marketers must not confuse consumers by using unfamiliar scientific words for common conditions.

12.5 Marketers inviting consumers to diagnose their minor ailments must not make claims that might lead to a mistaken diagnosis.

12.6 Marketers should not falsely claim that a product is able to cure illness, dysfunction or malformations.

12.7 References to the relief of symptoms or the superficial signs of ageing are acceptable if they can be substantiated. Unqualified claims such as "cure" and "rejuvenation" are not generally acceptable, especially for cosmetic products.

12.8 Marketers must hold proof before claiming or implying that a minor addiction or a bad habit can be treated without effort from those suffering.

Amendment D (CAP) →

12.9 Marketers must not encourage consumers to use a product to excess and must hold proof before suggesting their product or therapy is guaranteed to work, absolutely safe or without side-effects (subject to rule 12.19).

12.10 Marketing communications must not suggest that any product is safe or effective merely because it is "natural" or that it is generally safer because it omits an ingredient in common use.

Medicines

Amendment E (CAP)

Title VIII of European Directive 2001/83/EC (as amended) concerns "The Advertising of Medicinal Products for Human Use" and has been implemented in the UK by the Human Medicines Regulations 2012. Advertisements for products subject to licensing under the Human Medicines Regulations 2012 must comply with the requirements of the Regulations and any conditions contained in the marketing authorisation, certificate, licence or traditional herbal registration for the advertised product.

For more information on medicinal products and medical devices, go to: www.mhra.gov.uk. For more information on medical treatments, go to: ~~www.healthcarecommission.org.uk~~ www.cqc.org.uk.

Amendment E (CAP)

Advertisements for products subject to authorisation under the Veterinary Medicines Regulations must comply with the requirements of the Regulations and any conditions contained in the marketing authorisation, certificate or registration for the advertised product.

For more information please see Veterinary medicines Guidance Note 4 Controls on advertising (http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx)

Amendment B (CAP)

12.11 Medicines must have a licence from the MHRA, VMD or under the auspices EMA before they are marketed. Marketing communications for medicines must conform with the licence 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 rule 12.2.

Amendment B (CAP)

Marketing communications must not suggest that a product is "special" or "different" because it has been granted a licence by the MHRA, VMD or under the auspices EMA.

12.12 Prescription-only medicines or prescription-only medical treatments may not be advertised to the public.

12.13 Marketing communications which include a product claim for a medicinal product (including legible on-pack product claims within a pack shot) must include the name of the product, an indication of what it is for, text such as "Always read the label" and the common name of the sole active ingredient, if it contains only one.

Marketing communications for a traditional herbal medicinal product or a homeopathic medicinal product must include mandatory information, which can be found in the MHRA's The Blue Guide: Advertising and Promotion of Medicines in the UK at www.mhra.gov.uk.

Amendments F/G/H (CAP)

12.14 ~~Marketers must not use fear or anxiety to promote a medicine or a recovery from illness, and must not suggest that using or avoiding a product can affect normal health.~~ Marketing communications for medicinal products must not:

Amendment I (CAP)

12.14.1 use, in improper, alarming or misleading terms, images of changes in the human body caused by disease, injury or a medicinal product.

Amendment G (CAP)

12.14.2 refer, in improper, alarming or misleading terms, to claims of recovery.

Amendment F (CAP)

12.14.3 suggest that using or avoiding a product can affect normal health.

Amendment H (CAP)

12.14.4 present a description or detailed representation of a case history that might lead to erroneous self-diagnosis.

12.15 Illustrations of the effect or action of a product should be accurate.

12.16 Marketing communications for a medicine must not be addressed to children.

12.17 Marketers must not suggest that a medicinal product is either a food or a cosmetic.

12.18 Marketers must not use health professionals or celebrities to endorse medicines.

Amendment D (CAP)

12.19 Marketing communications for a medicine may not claim that its effects are guaranteed, that it is absolutely safe or without side-effects or as good as or better than those of another identifiable product.

12.20 Homeopathic medicinal products must be registered in the UK. Any product information given in the marketing communication should be confined to what appears on the label. Marketing communications must include a warning to consult a doctor if symptoms persist. Marketing communications for an unlicensed product must not make a medicinal or therapeutic claim or refer to an ailment unless authorised by the MHRA to do so.

Amendment I (CAP)

12.21 Marketers of traditional herbal medicines may advertise for the indications listed in the product's summary of product characteristics and must include mandatory information, which can be found in the MHRA's The Blue Guide: Advertising and Promotion of Medicines in the UK at www.mhra.gov.uk. Marketing communications for products that hold a Traditional Herbal Medicines Registration must not imply that registration is based upon clinical trials.

12.22 Claims made about the action that a cosmetic has on or in the skin should distinguish between the composition of the product and any effects brought about by the way in which it is applied, such as massage. Scientific evidence must also make that distinction.

12.22.1 Some cosmetics have an effect on the type of skin changes that are caused by environmental factors. Marketing communications for them may therefore refer to temporarily preventing, delaying or masking premature ageing.

Hair and scalp

12.23 Marketers must be able to provide scientific evidence, if relevant consisting of trials conducted on people, for any claim that their product or therapy can prevent baldness or slow it down, arrest or reverse hair loss, stimulate or improve hair growth, nourish hair roots, strengthen the hair or improve its health as distinct from its appearance.

Services offering advice on unplanned pregnancy

12.24 Marketing communications for services offering advice on unplanned pregnancy must make clear 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, marketers may wish to seek legal advice.

9. Annex 3: Summary List of the Consultation Questions

Amendment A (CAP)	**Question 1**	Do you agree with the proposal to add a “Scope” sub-section to Section 12? If not, please explain why.
	Question 2	Do you agree to the wording of the proposed “Scope” sub-section? If not, please explain why and include any alternative wording that you consider to be more appropriate.
Amendment B (CAP)	**Question 3**	Do you agree with the proposal to amend the “Background” sub-section and rules 12.1 and 12.11 of Section 12? If not, please explain why.
	Question 4	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 C (CAP)	**Question 5**	Do you agree with the proposal to add a new rule, 12.2.1, to Section 12? If not, please explain why.
	Question 6	Do you agree to the wording of the proposed rule? If not, please explain why and include any alternative wording that you consider to be more appropriate.
Amendment D (CAP)	**Question 7**	Do you agree with the proposal to amend rules 12.9 and 12.19 of Section 12? 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.
Amendment E (CAP)	**Question 9**	Do you agree with the proposal to amend the introductory text of the “Medicines” sub-section of Section 12? If not, please explain why.
	Question 10	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 F (CAP)	**Question 11**	Do you agree with the proposal to replace the relevant portions of rule 12.14 with rules 12.14.1 and 12.14.3? If not, please explain why.
	Question 12	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 G (CAP)	**Question 13**	Do you agree with the proposal to replace the relevant portion of rule 12.14 with rule 12.14.2? If not, please explain why.
	Question 14	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 H (CAP)	**Question 15**	Do you agree with the proposal to add a new rule, 12.14.4, to Section 12? If not, please explain why.
	Question 16	Do you agree to the wording of the proposed rule? If not, please explain why and include any alternative wording that you consider to be more appropriate.
Amendment I (CAP)	**Question 17**	Do you agree with the proposal to amend rule 12.21 of Section 12? If not, please explain why.
	Question 18	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.

Contact us

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