Annex C

CAP Medicines Consultation: Evaluation of Responses

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

Question 1: Do you agree with the proposal to add a "Scope" sub-section to Section 12? If not, please explain why.			
	Respondent making points <u>in favour</u> of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points <u>against</u> the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
2.1	**Proprietary Association of Great Britain (PAGB)**	We suggest an amendment to the proposed wording from "As they apply to…" to "As they could apply to...." to make it clear that the section applies to all marketing communications for medicine, medical devices, treatments, health-related products and beauty products so the materials in question may not fall under Human Medicines Regulations 2012 (HMRs) or Veterinary Medicines Regulations (VMRs).	CAP notes the respondent's point and has made the suggested amendment to ensure clarity on the application of the various rules to different products and therapies.

Amendment B (CAP) – References to European Medicines Agency (EMA) and Veterinary Medicines Directorate (VMD)

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.			
	Respondent making points <u>in favour</u> of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points <u>against</u> the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	

Amendment C (CAP) – Remote treatment and medicinal products

Question 5: Do you agree with the proposal to add a new rule, 12.2.1, to Section 12? If not, please explain why.			
	Respondent making points <u>in favour</u> of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points <u>against</u> the proposal:	**Summary of significant points:**	**CAP's evaluation:**
5.2.1	**Celesio UK t/a Dr Thom**	The proposals in this consultation do not appear to be aligned with those outlined in the Broadcast Committee of Advertising Practice (BCAP) consultation[1], specifically the proposed wording around the marketing communications for medicinal products. In 2012, the Department of Health published its information strategy; '*The power of information: putting us all in control of health and care information we need'*, which outlines the specific aim for '*the widespread use of modern technology to make health and care services more convenient, accessible and efficient'*. It is well documented and widely understood that the NHS is currently, and predicted to be more so in the future, facing unprecedented demands on resources and struggling with capacity. As the NHS in England continues to explore the development of plans around the introduction of on-line GP consultations and broadening access to NHS services via the use of the internet and smart phone apps, the amendments to the CAP Code appear to oppose the advertising of such services and thus work in opposition of the Government's aspirations.	Although BCAP's consultation concerns a different Code, CAP considers that the changes in its Code are in alignment with those of the BCAP Code. The relevant provision of the HMRs relates only to advertisements for medicinal products. CAP therefore does not consider that the proposed new rule would apply to the types of service referred to by the respondent. The rule would only be likely to apply if an advertisement for a service went so far as to indirectly promote a specific medicine. For instance, if an advertisement for a consultation on a particular medical problem or health related issue unduly emphasised a particular medicinal treatment in a manner that the ASA would be likely to consider indirect promotion.

[1] See BCAP Medicines Consultation

		[…] As the NHS in England continues to explore the development plans around the introduction of on-line GP consultations and broadening access to services via the use of the internet and smartphone apps, the proposed amendments to the CAP Code appear to oppose the advertising of such services and communication methods, and thus work in opposition of the Government's aspirations for healthcare.	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
6.1	**Celesio UK t/a Dr Thom**	No, we would propose wording that is in line with the BCAP proposals, which appears to relax the rules around prescribing by correspondence and is more closely aligned with the NHS direction of travel.	(see CAP's evaluation of response 5.2.1 above)
6.2	**PAGB**	Does "medicinal products" refer to/cover medicines only or medicines and medical devices? It doesn't appear to be clarified anywhere. If it applies to medicines only what is the reason for it appearing in this section (12.2.1, the "rules" section) and not the medicines section?	CAP considers that the Code makes the application of the rule sufficiently clear. The reference to "medicinal products" in the text of the rule, in conjunction with the various other references in Section 12 and the new "Scope" sub-section ensure that Code users understand its applicability. CAP also considers that the rule should appear in the general sub-section of Section 12. Although the primary intent of the provision is to focus on advertising of medicinal products by medicinal product manufacturers or distributors, the rule would also apply where, for instance, advertising for a service (e.g. a consultation service or clinic) went so far as to promote a medicinal product indirectly.

6.3	**A member of the public**	In my view, it may be appropriate to allow for remote diagnosis and treatment in a limited subset of cases. Since these cases will be difficult to enumerate in advance, should this rule be relaxed it must be made clear that such services are only to be offered if they have robust evidence of both (a) the safety and (b) the efficacy of any service offered, together with guarantees about the level of service required for complaints. Membership of professional bodies should not be acceptable as a proxy for these requirements, as the threshold of evidence and complaints handling procedures of professional bodies are very variable.	CAP's objective in this consultation has been to propose changes to the Code that ensure it is in line with the wider statutory framework relating to medicines. The proposed addition of rule 12.2.1 serves only this purpose; it does not relax the Code's approach. The Code already includes rule 12.2, which prevents marketers from discouraging essential treatment by requiring individuals offering advice or to diagnose or treat conditions for which medical supervision should be sought to be suitably qualified. The rule also establishes an approach requiring robust evidence of such individuals' suitability to offer services in relation to such conditions.

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

Question 7: Do you agree with the proposal to amend rules 12.9 and 12.19 of Section 12? If not, please explain why.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points against the proposal:	**Summary of significant points:**	**CAP's evaluation:**
7.2.1	**The Self Centre**	I feel that we should be able to advertise freely any products or therapies that we have bona fide scientific evidence to prove its effectiveness or testimonials from clients we have successful treated and we should be able to state that many of the products or therapies we offer do indeed have no side effects, unlike conventional drug and surgery based therapy on the NHS which is currently the public's only choice!	The amendment affects only medicinal products and harmonises the Code with the HMRs, which prohibit any claims about products being without adverse reactions, through the amendment to rule 12.19. CAP would point out that rule 12.9, as it relates to all products and therapies, does not prohibit marketers from making claims that products or therapies are guaranteed to work, absolutely safe or without side-effects. It merely requires that marketers should hold adequate substantiation.

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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
8.1	**Nightingale Collaboration**	We agree with the proposals that the wording of 12.9 and 12.19 be amended, but suggest the deletion of the word "absolutely" from the proposed wording for 12.19. We believe this would leave it open to an advertiser to make a claim that their medicine was 'safe' and then argue when challenged that they had not claimed it was 'absolutely safe' thereby circumventing the intention of 12.19 and Regulation 287. For the same reason, we suggest that 12.9 is amended to delete the word 'absolutely'.	CAP notes that the HMRs prohibit claims that taking a product is "not accompanied by any adverse reaction." CAP has maintained the wording "without side effects", drawn from the existing wording of rule 12.9, which, it considers, has the same meaning. Furthermore, CAP has decided, for consistency to include "absolutely safe" in the new wording of 12.19; As marketers cannot claim that a medicinal product is "without side effects", it is by definition not possible for them to claim that it is "absolutely safe". CAP would point out that it is not prohibited for advertisers to make claims that a product is "safe"; in the sense of not resulting in a particular adverse effect, e.g. drowsiness. The restriction is only on absolute claims that a product does not cause "any adverse reactions". CAP considers that the approach taken in the amendment, although at variance with the HMRs wording, it has the same meaning. In relation to the respondent's comment relating to rule 12.9, CAP would point out that the objective of the consultation was to make the necessary changes to the Code to ensure that it was in line with the underlying statutory framework. CAP considers that this point goes beyond the scope of this work as it relates to a rule not based on the HMRs.

Amendment E (CAP) – References to the Legislative Framework

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.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points against the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
10.1	**Medicines and Healthcare products Regulatory Agency (MHRA)**	We would suggest in response to questions 10 and 18 that it may be helpful to include a direct link to the Blue Guide at: http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/BlueGuide/index.htm.	CAP notes the respondent's point and has made the suggested amendment to ensure clarity on the application of the various rules to different products and therapies.

Amendment F (CAP) – Effects of a Medicinal Product

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.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points against the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	

Amendment G (CAP) – Material Relating to Diagnosis

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.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points against the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	

Amendment H (CAP) – 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.			
	Respondent making points <u>in favour</u> of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points <u>against</u> the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	

Amendment I (CAP) – Traditional herbal medicinal products

Question 17: Do you agree with the proposal to amend rule 12.21 of Section 12? If not, please explain why.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
	Respondent making points against the proposal:	**Summary of significant points:**	**CAP's evaluation:**
		[There were no significant points]	
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.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**CAP's evaluation:**
18.1	**MHRA**	We would suggest in response to questions 10 and 18 that it may be helpful to include a direct link to the Blue Guide at: http://www.mhra.gov.uk/Howweregulate/Medicines/Advertisingofmedicines/BlueGuide/index.htm.	CAP notes the respondent's point and has made the suggested amendment to ensure clarity on the application of the various rules to different products and therapies.

18.2	**A member of the public**	Yes, although I would ask here why there is a specific carve-out for one class of medical preparation. Although the MHRA allows the blue-book exemptions to the normal minimum standards of evidence, can the CAP be more consistent and hold all medicines to the same standards?	CAP's objective in this consultation has been to propose changes to the Code that ensure it is in line with the HMRs. The proposed changes to rule 12.21 are intended only to accomplish this. The question of whether the underlying statutory framework is appropriate is beyond the scope of this consultation.