Annex C

BCAP Medicines Consultation: Evaluation of Responses

Part 1: Services Offering to Prescribe or Treat Remotely

Question 1: Do you agree the proposal to amend rule 11.13.1 of Section 11? If not, please explain why.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
1.1.1	**Celesio UK t/a Dr Thom**	We welcome the proposed amendment and believe that this is aligned with the future direction of travel for the NHS, in supporting access to healthcare using more innovative and efficient methods where clinically appropriate.	BCAP agrees.
1.1.2	**Guild of Healthcare Pharmacists**	It would appear that appropriate safeguards for the public have been added to the re-wording by including reference to rule 11.9.	BCAP agrees.
1.1.3	**Pharmacy2U**	If a service provider is registered with the care quality commission to provide a particular service, for example the diagnosis and treatment of disease, then that service provider should be able to advertise that registered service.	BCAP agrees.
1.1.4	**Radio Centre**	RadioCentre has believed for some time that the extent of the restriction on services that offer to prescribe or treat remotely (such as online pharmacies) is disproportionate […] The strength of the prohibition in place at present is not reflective of changes in the market, and fails to take into account the regulatory safeguards in place to oversee the activities of health professionals are services. We also believe that there is a potential revenue opportunity for broadcasters and legitimate advertising opportunity for these companies. Therefore we welcome the proposal to relax this prohibition, in order to enable online pharmacies to advertise on radio (and TV) as long as they are able to satisfy the provisions of Rule 11.9 and provide suitable credentials. In radio this will rely on the	BCAP agrees.

		RACC (Radio Advertising Clearance Centre) has making this judgement in the first instance, which is an appropriate safeguard given the vast experience and expertise that the clearance team has built up over the years in considering such matters against this particular rule.	
1.1.8	**Royal Pharmaceutical Society**	We agree with the amendment which stipulates that the advertiser must have the credentials listed and the importance of this cannot be over emphasised. In respect of internet selling of medicines we would require that advertisements are from a registered pharmacy and therefore must comply with the standards and rules of our regulatory body, the General Pharmaceutical Council. It is our understanding that one of the major sources of counterfeit medicines is through unregistered internet pharmacies and this poses a significant risk to patient safety. In addition, the Royal Pharmaceutical Society is clear that medicines are not normal items of commerce and should not be treated as such. Encouraging consumers to buy more pharmacy-only medicines than they need will not improve the health of the public.	BCAP agrees. The proposal is intended to relax the rule by requiring that advertisers to demonstrate their suitable credentials as stipulated by rule 11.9. The clear focus is on allowing appropriately regulated services to advertise in broadcast media, while maintaining a restriction on those that are not subject to such regulation.
	Respondent making points <u>against</u> the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
1.2.1	**A member of the public**	As far as I can see, this relies almost entirely on the restrictions required under Code Rule 11.9. Although this requires that advertisers have "relevant professional experience or credentials", or "accreditation by a professional or regulatory body that has systems for dealing with complaints", this appears to me to be rather vague. Particularly (although by no means exclusively) outside "mainstream" medicine, there exist professional bodies who accredit their members, and yet whose required evidence base is of very low quality, and whose complaints procedures are inconsistently applied. In my view, the revised rule 11.13.1 must also include a requirement for robust evidence of both (a) the safety and (b) the efficacy of any service offered, together with guarantees about the level of service required from the complaints procedure.	Rule 11.9 is BCAP's general rule on the requirement for services, including clinics, establishments and the like, to hold suitable credentials for the advice and/or treatment they offer. The ASA's assessment of advertisements under the rule depends on the nature of the service offered. Nevertheless, BCAP considers that advertisers offering pharmacy services should conform to the standards set out in the relevant statutory regime. In relation to other services, the ASA will assess them on a case-by-case basis, but will have regard to whether a service includes face-to-face consultation and the structures of regulation underpinning it; one of the key functions of which

			should relate to patient safety. Furthermore, in relation to the respondent's concern over matters of efficacy, BCAP would point to the other rules in the Code requiring that advertisers are able to substantiate their claims.
Question 2: Do you agree to the wording of the proposed amendment? If not, please explain why and include any alternative wording that you consider to be more appropriate			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**BCAP's evaluation:**
2.1	**Guild of Healthcare Pharmacists**	The listed types of 'advertisements' used to sell products are rather specific. We feel this should also include social media and the use of 'apps' etc.	BCAP has used wording drawn from the Human Medicines Regulations 2012 (HMRs) Regulation 286 to ensure the approach is aligned with the regulatory framework for medicinal products. BCAP considers that "…by other means of an electronic communications network …" outlines the scope of the proposed amendment sufficiently and in a manner that would cover the examples cited by the respondent.

Part 2: Smoking Deterrents and Harm Reduction

Question 3: Do you agree with the proposal to amend rule 11.18.2 of Section 11? If not, explain why.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
3.1.1	**Proprietary Association of Great Britain (PAGB)**	PAGB member companies welcome the introduction of […] the amendments to the rule on smoking deterrents to ensure alignment with the medicines licence provisions, which allow NRT products to advertise harm reduction.	BCAP notes the respondent's point.
3.1.2	**Radio Centre**	We understand the need to update existing wording on smoking deterrents and harm reduction, in order for this to be consistent MHRA advice and other provisions in the BCAP Code. Given this is such a complex and evolving area – in terms of products, scientific evidence and licensing – it seems eminently sensible to look to the MHRA to determine whether or not a smoking deterrent product can make claims of harm reduction. Therefore we support the proposed amendment to rule 11.18.2.	BCAP agrees.
3.1.3	**Royal Pharmaceutical Society**	We understand that this aligns the wording with changes in the marketing authorisations regarding harm reduction.	This was BCAP's overriding intention in proposing the changes to the rule.
	Respondent making points against the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
3.2.1	**Royal College of Physicians**	The proposal is that 'advertisements for smoking deterrents must not claim that smoking is safer while the habit is being reduced, unless authorised to do so by the MHRA'. Our experts wonder whether the intention is for the MHRA to authorise every single advertisement. If so, this would be good but it is recognised that it would be a lot of work. That being the case, it might be reasonable to allow advertisements that	BCAP understands that, in line with its usual processes, the MHRA (or European Medicines Agency) will grant a licence for a product to make certain indications in its advertising. As such, the MHRA will approve the claim in a general sense, but

		claim to reduce the harm from smoking as a step towards complete cessation.	not individual advertisements. BCAP would stress that the Code is based on the requirements of the medicines advertising framework including provisions governing the handling of complaints about TV and radio advertisements that fall under certain provisions of HMRs. BCAP is therefore confident that the Code is well placed to ensure that advertisements able to make harm reduction claims do so in way that is responsible, not likely to mislead consumers and is in accord with the provisions of the product's medicines license.
Question 4: Do you agree to the wording of the proposed amendment? If not, please explain why and include any alternative wording that you consider to be more appropriate			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**BCAP's evaluation:**
4.1	**Action on Smoking and Health (ASH)**	ASH supports the proposal to amend this rule in order to avoid any potential conflicts with other sections of the code. However, as there is no safe level of tobacco use we think it is unlikely that the MHRA (Medicines and Healthcare Product Regulatory Agency) would authorise an advertisement which claimed that a certain level of smoking was "safe" while the habit was being reduced.	BCAP acknowledges the respondent's point that the MHRA are very unlikely to authorise claims that smoking fewer cigarettes is "safer". BCAP did note this in the consultation document but considered also that the term "safer" could include harm reduction claims and thereby the rule could contradict the MHRA's decision to license such claims for NRT products. Nevertheless, BCAP is concerned that the proposed wording is not sufficiently clear and as therefore amended it to make clear that an exemption exists for advertisements making harm reduction claims that are authorised by the MHRA.

4.2	**PAGB**	We appreciate that this comment relates to the current text, as opposed to the proposed new wording, however we believe that 'is safer' isn't appropriate wording. We wouldn't use the term 'safer' in advertising. Also, the proposed wording could be interpreted to mean that if you are cutting down the number of cigarettes you smoke, the cigarettes you smoke during this time are 'safer' than the ones you would smoke if you weren't cutting down. We understand that the intention of the update of this section in the BCAP Code is to reflect the harm reduction indication for NRT products, as approved by the MHRA and included in the SmPC (Summary of Product Characteristics) for several NRT products. However, as it is currently presented, rule 11.18.2 is ambiguous and it inaccurately replaces the 'harm reduction' concept with safety. In our view, the rule should highlight that harm reduction messages can only be made if the SmPC permits it. Until recently, SmPCs encouraged people not to smoke cigarettes at all while using NRT but it is known that substituting NRT for some cigarettes has been a method used by some people and this is now reflected in the harm reduction indications in licences. We think that the rule 11.18.2 could contain further explanations to describe this context and remove any ambiguity, i.e. people not being misled into believing that if they are cutting down the number of cigarettes they smoke, the cigarettes they smoke during this time are 'safer' than the ones they would smoke if they weren't cutting down. It should be made clear to the consumers that by cutting down the number of cigarettes smoked and replacing these with an NRT product they are reducing the harm to others from passive smoking and to themselves through reducing exposure to the tar and other toxins present in cigarettes. PAGB is of the opinion that a greater level of explanation would be useful to be included in this section of the BCAP Code.	(see the evaluation of comment 4.1 above)
4.3	**Royal Pharmaceutical Society**	We would advise that the rational be made clearer in the statement e.g. “unless authorised to do so by the MHRA.” Could be changed to something like “unless this is in accordance with the terms of the marketing authorisation issued by the MHRA “	(see the evaluation of comment 4.1 above)

Part 3: Technical Updates Reflecting Legislation

Question 5: Do you agree with the proposal to amend the "Law" sub-section of Section 11? If not, please explain why.			
	Respondent making points <u>in favour</u> of the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
		[There were no significant points]	
	Respondent making points <u>against</u> the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
		[There were no significant points]	
Question 6: Do you agree to the wording of the proposed amendments? If not, please explain why and include any alternative wording that you consider to be more appropriate.			
	Respondent making points on the wording of the proposal	**Summary of significant points:**	**BCAP's evaluation:**
6.1	**Guild of Healthcare Pharmacists**	The new wording has suitably replaced outdated references to previous legislation. We wondered, however, about the amended wording for revoking *The Veterinary Medicines Regulations* which has changed from "annually" to "regularly". There appears to be no reason for this amendment, and how regular is 'regular'?	BCAP sought the pre-consultation advice of various key stakeholders including the Veterinary Medicines Directorate (VMD). It was on their advice that this minor amendment to the wording was made in accordance with BCAP's stated objective to make amendments to the Code to ensure that it is better aligned with the relevant statutory frameworks.

Question 7: Do you agree with the proposal to amend the "Background" sub-section and rules 11.4 and 11.19 of Section 11? If not, please explain why.			
	Respondent making points in favour of the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
		[There were no significant points]	
	Respondent making points against the proposal:	**Summary of significant points:**	**BCAP's evaluation:**
		[There were no significant points]	
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:**	**BCAP's evaluation:**
8.1	**Guild of Healthcare Pharmacists**	The new wording correctly reflects the granting of licenses by the European Commission under the auspices of the EMA, and mentions the MHRA at appropriate points.	BCAP notes the respondent's point.