Ethics Committee Telecon	
Date:	**24 June 2014**
Event:	**Ethics Committee Meeting**
Time:	11.30 – 14.00
Place:	Teleconference
Participants:	Bob Douglas (BD)
	Bernadette Rogers (BR)
	Catherine Ayland (CA)
	Christine Mai (CM)
	Georgina Butcher (GB)
	Karen Giorgi Vigo (KGV)
	Piergiorgio Rossi (PR)
	Roni DasGupta (RDG)
	Xander Raijmakers (XR)
Distribution List:	Participants
Apologies:	Peter Eichhorn (PE)
	Solvea Lamarina (SL)
Minutes by:	Catherine Ayland (CA)

ACTION POINTS			
No.	**Action**	**Timeline**	**Responsibility**
1.1	CM is to find out if it is possible for EphMRA to circulate the letters to its members.	July	CM
	BR is to get the letter translated into English.	July	BR
	CA to issue new Loi Anti-Cadeaux update relaying the information in the ASOCS letter (once the translation is available).	July	CA
	CA to check source material and add new Loi Bertrand question and response to the online series of FAQs (to explain/confirm that 15 day reporting is no longer required) and an additional Loi Anti-Cadeaux question and answer on donations.	July	CA
	EC requested that BR explore the possibility of PMRG, CASRO and ESOMAR advertising EphMRA as a key source of information upon the Loi Bertrand and Loi Anti-Cadeaux. BR has suggested that this forms part of the Ethics PR/Comms plan, see point 6.	July	CA
	CA to include a reference in the 2015 Code to VfA requirements and to draft a question for inclusion within	October	CA

	a recruitment screener to cover this issue with a view to exploring VfA/FSA approval for its use.		
1.3	In the absence of any further EphMRA generated potential nominees to co-ordinate/support the extension of the Code to Turkey, the EC will be asked to suggest potential people, if these fail to produce any action, the inclusion of Turkey will be reviewed at the September EC meeting. BR to try to find potential members to co-ordinate/support the extension of the Code to Australia and Canada and initiate contact, CA will follow up if the nominees are willing and able.	September July	CA & All BR
1.4	Member consultation period for the annual Code review to be reduced from 6 to 4 weeks (from 2 to 30 Sep) to allow late October, early November EC review	September	CA & BR
2.1	BR to re-open the Code Mark questionnaire and email members to advise them of this, closing the extension on 18 July. BR to organise data processing of questionnaires.	July September	BR BR
3.1	CA to re-circulate the additional guidance upon 'Research Ethics Committee Approval & Market Research' to EC members for their review, feedback by 15 July	15 July	CA & All
5.1	CA to circulate the outline of the AER training currently in development and EC to provide any feedback by 15 July. XR and KGV volunteered to try to pass on copies of their company's internal AER training for comparison with the EphMRA draft. CA to check the EMA terminology used to describe AEs and this should be adopted for the AE training. Translation of AER training materials and the accompanying competency test - it was agreed that CA would raise this issue with BR and seek information about next steps to explore the issue (which might include costs, charges, assessment of the need, Board reaction). BR has advised that the first step would be to ensure there is a clear EC view (consensus) on the value of providing translations and this would need to be considered by the Board (because of the significant cost implications). The EC would need to provide a rationale to support the case for spend on translations (as appose	15 July 8 July July September	CA & All XR & KVG CA CA & BR

	to other ethics initiatives).		
5.2	The EC requested a pro forma for the key information required, CA to draft first outline and forward to BR for Sally Birchall, chair of the Forward Thinking group, EC will also consider the pro forma and advise on the practicality of collecting this information	September	CA & BR
6.1	CA to revise the goals of the any potential PR/Comms initiatives, update the Beattie paper with these and the need to promote our ethics expertise (e.g. on Loi Bertrand) to other organisations and circulate it before the September EC meeting so that EC members can consider the suggestions and be ready to discuss and agree them at the meeting. This may need to be via email prior to the September EC meeting so that a PR/Comms programme can be put in place asap, ideally in time for the Code Consultation invite in early September.	July August	CA to revise goals All to review goals and suggestions
7.1	Training suggestions to be reviewed and feedback on them from the EC to be given via email.		
8.1	BR to find out from CASRO if it practical for EphMRA to share the 'Self-Regulation Advocacy, Pharmaceutical Market Research, A CASRO Report' with members (via online access on the EphMRA website). CA to provide more information about the GRBN to the EC before the September EC meeting.	July August	BR CA
Date of next meeting 12 September 2014, 2 - 3pm (UTC), CA to circulate invite and agenda.		September	CA

[The number above relates to the items below]

MINUTES		
No.	**Topic**	**Comment**
1	**Code of Conduct**	**1.1 Ongoing Issues** **France, Loi Bertrand** CM provided a copy of a letter dated 31 May sent by the ASOCS President (but not available on the ASOCS website) updating ASOCS members on progress for redefinition of the Loi Anti-Cadeaux reporting requirements. CM reported that the letter said that the plan is to type MR studies into 4 or 5 groups and that companies/agencies will be required to report the number of HCPs in each type of study for the coming year. Then during the course of the year the estimates

		should be updated with actual numbers and names and incentives paid added. There was no indication in the letter that public disclosure of this information would be required. The letter also stated that until the new reporting requirements are finalised no reporting for Loi Anti-Cadeaux purposes is required. CM is to find out if it is possible for EphMRA to circulate the letters to its members. BR is to get the letter translated into English. CA to issue new Loi Anti-Cadeaux update relaying the information in the ASOCS letter (once the translation is available). BD raised the question of a 15 day reporting period required for Loi Bertrand however CM explained that this is no longer required and provided a reference to check this information. CA to check source material and add new Loi Bertrand question and response to the online series of FAQs (to explain/confirm that 15 day reporting is no longer required). The issue of whether incentives given as donations direct or indirect have to be reported for Loi Anti-Cadeaux was raised and CM confirmed that they do in all circumstances. A question and answer covering this will be added to the FAQs. The EC also discussed the importance of publicising the two laws in France and suggested involving PMRG, CASRO and ESOMAR in this and asked if BR could facilitate this, referencing EphMRA/website as a key source (even though most of the information is for members only). **Germany, Dienstherrengenehmigung/Employer permission** BR has followed up with FSA lawyer but no response yet and CA is still awaiting notes for the German Chapter meeting. CA to include a reference in the 2015 Code to VfA requirements and to draft a question for inclusion within a recruitment screener to cover this issue with a view to exploring VfA/FSA approval for its use. **1.2 Extensions underway - update**. **Turkey** – No progress due to lack of response from 3 different potential local co-ordinators/supporters. In the absence of any further EphMRA generated potential nominees to co-ordinate/support the extension of the Code to Turkey, the EC will be asked to suggest potential people, if these fail to produce any action, the inclusion of Turkey will be reviewed at the September EC meeting **India** – Still under review with Ipsos legal team **China** – There is nothing further to report. **1.3 2015 extensions** There are 16 countries included at present. Suggested countries for inclusion in the 2015 Code update – Australia, Benelux, Canada, Greece, Mexico, Middle East/Saudi Arabia, Portugal, and Turkey. Australia, Canada and Turkey were nominated as the EC's highest priorities. **1.4 Timetable for 2015 update**

		CA raised a concern about meeting the timetable for the annual update, the current schedule requires EC review and feedback in December proved difficult in 2014 because of pre-Christmas workloads (leading to a delay in releasing the update) and so asked to EC to reconsider the timetable for input and updating. The clear conclusion of the discussion was to limit the period for member feedback to 4 weeks (from 2 to 30 Sep), the update to be completed by 24 October by CA and EC feedback to be given by 7 November. This will ensure Code publication at the beginning of 2015.
2		**2.1 Code Mark** Consultation exercise (short questionnaire to establish whether the initiative would be of value and to get feedback on a possible format) with full members was completed in June, 13 responses were received. The EC have requested an extension of 2 weeks to try to generate more replies. BR to re-open the questionnaire and email members to advise them of this, closing the extension on 18 July. BD did advertise this within the Ethics Update at the Conference. BR to organise data processing of questionnaires.
3	**Research Ethics Committee Approval & Market Research**	**3.1 Additional guidance** Following a request made that the EC look at developing some form of more detailed guidance on the need for ethics approval and the circumstances when this impacts market research, a draft has been developed and was circulated on 27 May for the EC for review prior to the meeting. The EC requested more time to do this – 2 weeks. CA to re-circulate, EC members to feedback by 15 July.
4	**EFPIA Disclosure Code**	**4.1 Update** Currently awaiting confirmation that the EFPIA questions within which the MR exclusion is included have been published and then this news will be circulated to members (an update has already been prepared). **4.2 Reaction to FM co-ordinated action to examine the impact on companies** The FM member suggestion to investigate the impact on FMs of the Disclosure Code will not go ahead as the results would need to be available by September 2014 and so the time is too short
5	**Adverse Event Reporting Guidelines & Training**	**5.2 AER Training – Update** Development is well underway, a detailed outline of the proposed approach was shared with the EC at the meeting (BD talked through the key aspects) and the EC were asked for feedback on the content areas of the training. The EC requested 2 weeks to provide their feedback. CA to circulate the outline and EC to provide any feedback by 15 July. BD informed the EC that EphMRA have reached agreement with the BHBIA with regard to testing – there is to be a complimentary test rather than a joint test. There was some debate about the most appropriate terminology to be used within the training, whether AE was an appropriate umbrella term (encompassing adverse events, adverse reactions, product complaints and special reporting

		situations) or not. There was acknowledgement that using all these terms throughout the training would make it cumbersome and that different companies use different terminologies (some using safety data as an umbrella term). CA proposed that the EMA terminology is checked and that this is adopted. XR and KGV volunteered to try to pass on copies of their company's internal AER training for comparison with the EphMRA draft. There was discussion of the value that EFPIA or EMA endorsement would add to the training and it was proposed that EphMRA should try to secure this but that release of the training will not wait for this. The EC considers this an important goal. In addition, this question of whether translations of the AE training and/or just the accompanying competency test could be made available was raised and discussed. There were mixed views expressed – the probable high cost of the initial translation and maintaining it were a clear disadvantage but countered by the need for certified training for local interviewers that do not speak English. It was agreed that the issue should be raised with BR by CA and advice/information about next steps to explore the issue sought, which might include costs, charges, assessment of the need, Board reaction. **5.2 Forward Thinking Project - AER.** Following forwarding of the brief to EC FMs there has been only 1 response. The EC requested a pro forma for the key information required, CA to draft first outline and forward to BR for Sally Birchall, chair of the Forward Thinking group for circulation, EC will also consider the pro forma and advise on the practicality of collecting this information. The suggestion was also made that agencies could be contacted to find out what proportion of AE reports forwarded result in a request for follow up for further information.
6	**PR for Code of Conduct and Competency Testing**	**6.1 Need for PR and discussion of suggestions** Beattie Communications have put forward some suggestions to raise awareness and boosting member engagement for the Ethics Committee. This includes raising the profile of the EC's work and the revamping Code Corner. The suggestions fit within our current budget allocation were discussed. Other ideas which would increase the Communications budget can be assessed but would be subject to budget allocation from October onwards. A short paper (by Beattie) with goals and suggestions was introduced at the meeting but there wasn't the time to digest or discuss the detail and the EC requested time to review and respond to the suggestions. There was some immediate feedback on the goals and it was suggested that these are revised and then the paper is circulated for consideration before the next EC meeting in September, where the PR/comms suggestions will be discussed. PR to promote the Code, training and competency test were discussed at the EC meeting, the EC requested time to think about the suggestions and revisions to

		the goals. With discussion of PR to members, the issue of PR/communicating with non-members was raised and it was suggested that some form of joint initiative with both MR and non-MR organisations (e.g. ESOMAR and regulators, EFPIA were mentioned) could be considered. This issue will be raised again at the September EC meeting. Again, the issue of regulator endorsement (for the Code and training) was raised. Website development – the suggestion for an ethics 'front ' page to provide an access point to the (many) ethics resources on the website has been made and will be reviewed once the web analytics data has been reviewed and the issue will be discussed at the September EC meeting as time ran out on this issue. The BHBIA rewrite (of their Guidelines – redrafted by a professional writer/communicator to make them as easy to follow as possible) was also raised and it was suggested that EphMRA consider something similar as another means to make the Code more accessible. It was pointed out that this would involve additional costs.
7	**Webinar plans**	**7.1 Suggestions** Time for discussion of this issue at the EC meeting ran out so it was agreed that suggestions will be considered via email (there are no webinars planned at present). The following suggestions were drawn from Evaluation questions from events and webinars (they date from June 2013 to date) but other ideas are welcome too: ▪ Differences from country to country, or EU and non-EU ▪ Big data ▪ Disclosure requirements – EFPIA, USA, France ▪ General basic introduction ▪ Update
8	**Liaison with other organisations**	**8.1 Update** Building productive relationships with outside organisations that can impact MR or can help promote EphMRA's Code, training and healthcare ethics expertise was an issue that occurred several times during the meeting and is a high priority for the EC. There was a brief review of the current status of relationships: International organisations: ▪ **EFPIA** – Relations are very positive following the 29 April meeting ▪ **EMA** – EphMRA has a contact on the AER side and have been represented at an EMA meeting ▪ **ESOMAR** – In regular contact with and have good relations with their Professional Standards group, ran first joint training webinar in April 2013 ▪ **GRBN** – EphMRA does not have any links with the GRBN at present but was aware of their existence and role, the EC wondered whether it is worth EphMRA's while to foster links or to consider membership, more information about the organisation was requested, CA to follow this up. National Associations:

		▪ **ADM** (Germany) – Have had some contact ▪ **ASOCS** (France) – have had some contact ▪ **BHBIA** (UK) – Have regular contact and productive relationship that has resulted in joint initiatives on competency testing ▪ **CASRO** (USA) – After an approach was made for access to CASRO resource on the Sunshine Act, CASRO has sent a document 'Self-Regulation Advocacy, Pharmaceutical Market Research, A CASRO Report' that details the positions and arguments made in the US to separate market research from regulations designed to bring transparency to pharma marketing activities with physicians. The report was published by the 'Global Research Business Network' (an over-arching organization to which APRC, EFAMRO and ARIA are affiliated). At present it is not clear of EphMRA can share this information with members, BR is to find this out. BR has informed CASRO we will review and get back to them only if we have questions or comments. ▪ **FSA** (Germany) – we met at the EFPIA meeting.
9	**New chair of Ethics Committee**	**9.1 Update** Two new co-chairs were welcomed to the Ethics Committee: ▪ Georgina Butcher, Marketing Intelligence, Astellas, current EphMRA Board member and founding member of EC ▪ Ian Barker, Head of Compliance & Information Security at Ipsos Bob Douglas has stepped down as an EC member and chair and was thanked for his commitment and hard work on behalf of EphMRA's Professional Standards team.

COMMITTEE MEMBERS ARE ASKED TO RESPECT THE CONFIDENTIALITY OF THE INFORMATION THAT IS EXCHANGED DURING COMMITTEE DISCUSSIONS – THANK YOU.