

<b>Ethics Committee</b>	
<b>Date:</b>	<b>12 September 2014</b>
<b>Event:</b>	<b>Ethics Committee Telecon</b>
<b>Time:</b>	14.00 – 15.00
<b>Place:</b>	Teleconference
<b>Participants:</b>	Bernadette Rogers (BR) Catherine Ayland (CA) Georgina Butcher (GB) – Co-Chair Ian Barker (IB) – Co-Chair Karen Giorgi Vigo (KGV) Peter Eichhorn (PE) Xander Raijmakers (XR)
<b>Distribution List:</b>	Participants
<b>Apologies:</b>	Solvea Lamarina (SL), Christina Mai (CM), Piergiorgio Rossi (PR), Roni DasGupta (RDG)
<b>Minutes by:</b>	Catherine Ayland

#### ACTION POINTS

No.	Action	Timeline	Responsibility
1.1	Summary Code Mark document to be sent out to Committee members after the meeting. Responses to BR in the next 2 weeks.	By 30 Sep	CA/GB & BR
3.1	Review of AER Training document	TBC	GB, IB, XR, RDG
4.1	The 3 full members to review the questions to ensure they are meaningful for PV. CA to send out.	By 30 Sep	GB, KGV & XR
5.1	PR & Comms goals (draft) to be circulated for comment.	By 30 Sep	CA
6.1	The Public Affairs draft document to be circulated for feedback plus list of all organisations considered	By 30 Sep	CA
7.1	Contact for Turkey Code extensions to be forwarded	By 30 Sep	GB/IB

[The number above relates to the items below]

#### MINUTES

No.	Topic	Comment
<b>1</b>	<b>Code of Conduct Code Mark</b>	<b>1.1 Feedback on Questionnaire.</b> In May this year EphMRA emailed full members to gain views via a questionnaire on the draft proposal regarding the Code Mark. Responses were from a range of companies but not enough to help make firm decisions. There is interest in it, but questions were raised and some drawbacks pointed out. Another option raised in August, as an interim step would be to set up a voluntary online register of the associate members who've conducted the training on the Code. For full members it would be a very useful tool to allow them to identify more easily which agencies/researchers have actually conducted the training. A summary document will be circulated after the meeting. It was asked what level of detail is expected. In terms of further detail, once there is agreement that this is a good way to proceed then we can work out more detail.

		Changes in the member's area of the website can be made to accommodate such a register.
<b>2</b>	<b>National Issues</b>	<p><b>2.1 France Loi Bertrand &amp; Loi Anti-Cadeaux.</b> BR recently met with a representative from SYNTEC to discuss the Loi Bertrand and the I Anti-Cadeaux. Negotiations are ongoing with CNOM with regard to restructuring the format of feedback for Loi Anti-Cadeaux. SYNTEC feel they have more possible room for flexibility in terms of looking at the practical implications of what people are being asked to do. They have been left with the list of outstanding queries from EphMRA. However, they don't have the answers to them yet.</p> <p><b>2.2 Germany – Employer permission</b> BR met with BVM to discuss the employers' permission for MR in Germany. In September, the DKG met with the FSA to discuss the FSA position. An outcome paper from that meeting is to be issued, soon. BR is assured that when it is issued, a copy will be given so EphMRA can get it translated.</p> <p>It was noted that late-November is when the Code update should be nearly finalised, and it is likely that Germany will have an updated decision in time for this. Revisions can be done during December and the update to be definite by year end.</p>
<b>3</b>	<b>AER Training</b>	<p><b>3.1 Outline of AER Training.</b> A draft will be available soon of the outline of the training, which pulls on all the material supplied from the 2 pharma companies (Shire and J&amp;J), plus the BHBIA materials and member feedback. There is a draft Word doc outlining the training module. This will be ready for small group review w/c 15 September and once that's agreed we can move forward to look at developing the test questions. The scope was agreed. GB, IB and XR agreed to be part of this small review group. RDG was added to the review group after the meeting.</p> <p><b>3.2. Translation Policy.</b> There has been much discussion over time regarding translations of EphMRA materials, but given the requirements for regular updating, version control and accuracy required it was agreed at Board level for materials to be produced in English only. This decision is unlikely to change for the foreseeable future.</p>
<b>4</b>	<b>Adverse Event Reporting</b>	<p><b>4.1 Forward Thinking Group Project.</b> The scope of the research project has changed over time due to difficulties in accessing the information required for the original goals. There is recognition at Board level and within the membership that this is an important topic, but the information collection challenges it poses are recognised. A revised approach has been proposed, the first stage of which will involve a very short questionnaire to gain input from FMs' PV departments (with the possibility of further follow up to be discussed). The EC's 3 FMs are to review the questions asked and once the question format is finalised, they will approach their PV colleagues to assess the feasibility of collecting the information.</p>
<b>5</b>	<b>PR for Guidelines and Competency</b>	<p><b>5.1</b> We want to put some objectives around what the goals for PR would be so that they can be clearly communicated to the PR agency and to also use this as a stepping stone to ensure we have that PR program in place to promote the guidelines and competency testing to both EphMRA members and beyond. So</p>

	<b>Testing</b>	the Ethics goals have been drafted and CA will circulate these for comment.
<b>6</b>	<b>Public Affairs</b>	<p><b>6.1</b> This refers to building and managing external relationships, which involves liaising with contacts in complementary industry bodies e.g. ESOMAR, CASRO in the US. A good example is the work with SYNTEC and ASOCS, to be able to have that ongoing discussion and relationship with them, so we can align and use our shared knowledge and power for lobbying.</p> <p>A document has been developed to highlight and prioritise which of those agencies or organisations we should be targeting and to identify what the objectives are in our relationship with those organisations. For example, EMA; what are the short, medium and long term goals?</p> <p>Following discussion, there will be a document circulated for comment, showing priority organisations and suggested goals for a quick review plus a list of those organisations considered for comment.</p>
<b>7</b>	<b>AOB</b>	<b>7.1</b> We currently have only one viable country - Greece. Others are taking longer and need to keep momentum. There is a possible contact in Turkey. Belgium to be possibly looked at also.
	<b>Next Meeting</b>	13 November 2014 (Co-Chair Ian Barker)

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