

Ethics Committee	
Date:	5 February 2015
Event:	Ethics Committee Telecon
Time:	1400 – 1500
Place:	Teleconference
Participants:	Bernadette Rogers (BR) Catherine Ayland (CA) Christine Mai (CM) Ian Barker (IB) – Co-Chair Peter Eichhorn (PE) Piergiorgio Rossi (PR) Roni DasGupta (RDG)
Distribution List:	Participants
Apologies:	Georgina Butcher (GB), Karen Giorgi Vigo (KGV), Xander Raijmakers (XR), Solvea Lamarina (SL)
Minutes by:	Catherine Ayland

ACTION POINTS			
No.	Action	Timeline	Responsibility
1.1	Recommend to the Board that no further time or resource is put into the 'Collection of evidence on the quality of the AER' initiative	Feb/Mar	BR
2.1	Next steps for the development of the Code Competency Voluntary Online Register will include writing to companies with code certified personnel to ask if they wish to go on the register	Feb/Mar	BR
3.1	Code of Conduct extensions priorities to be sent back in by all EC members in response to CA request via email	20 Feb	CA/EC
3.1	Code of Conduct extension recommendations to go on Board March meeting agenda	w/c 23 Feb	BR
4.1	Fill the gaps in the disclosure requirements in France and Italy	Next EC meeting	CM and PR
	Raise geographical scope of Code and country/territory priorities at Board level, via Georgina's report to secure Board guidance to help prioritise extension countries	Feb/Mar	BR and GB
	Add taking public affairs forward to the agenda for next meeting	Next EC Meeting	CA

[The number above relates to the items below]

MINUTES		
No.	Topic	Comment
1	Collecting evidence on AER	1.1 The purpose of this was to collect evidence on the quality of adverse events reports generated from market research. 4 companies were asked if they could assist and only 1 company has responded. The current recommendation is we ask the Board that we shelve this initiative and this was agreed.

2	Code of Conduct Competency Certification – Voluntary online register	<p>2.1 The stats have been received on the competency certificates and they have been analysed. Analysis is by company, how many have taken, passed and got their certificate and the code of conduct competency test.</p> <ul style="list-style-type: none"> • EphMRA are going to write to these companies in the next week and ask if they would like to be included in the list. • The list will show the time period and the number of people, the number of code of conduct competency tests that have taken and passed in that time period. • The list will be in the members’ area of the website. • In order to drive uptake of the code of conduct test and certification, everyone will be asked if they will also give permission for EphMRA to use their names and figures in PR and communications. • Will update again at the next EC meeting.
3	Code of Conduct extensions	<p>3.1 EC will bring forward review of countries to consider extending the code of conduct to. To give more time to incorporate more countries the need is to start thinking about this now.</p> <ul style="list-style-type: none"> • In the agenda is a list of suggested countries for extending. • Ethics Committee members to advise CA what their priorities are in terms of which countries they would most like to see included in the next draft of the code of conduct, allocating either a high, medium or low priority to the countries that have been listed and to provide some supporting arguments or rationale – why do you think this country or that country is a high priority and why others are a lesser priority, to aid decision making. • It was pointed out by some EC members that as we are a European organisation we should have a high priority on all European countries on the list. • The feasibility of securing support/resource locally is another factor to consider. If after first contact there is not much response coming back we need to be realistic. So for example, if Australia is not responding after 3 levels of contact we also involve other EC members in securing contacts or prioritise other countries. • In terms of EphMRA scope at Board level it is across all areas not just Europe. Is Europe the highest priority in terms of territories to which EphMRA seeks to reach out? There’s quite a lot of discussion at Board level about geographical reach so via Georgina in her report, ask the Board if it was fine to allocate resources to countries outside Europe. The next Board call is towards the end of March and then June so to get this through need feedback by 20 Feb. • Regarding making contact with Australia. PE has an MD in Australia and a dedicated health team in Australia who might be able to help. We can use Peter’s name when making contact. Roni does not have contacts in Australia, but has Canada contacts. • BR or CA will come back to Roni once list of definite countries and see what’s needed.
4	Any Other Business	<p>4.1 Need to pull some information together on different disclosure processes happening in the different countries that the code covers. We are struggling in</p>

		<p>terms of gap filling. France and Italy have gaps.</p> <ul style="list-style-type: none"> • Send an email to PR and CM to ask a short series of questions i.e. whether data protection is a limitation, who is the organising body in their country and whether there are any differences on the reporting form, so that we can try and put out a country by country sheet for members saying this is how disclosures are going to be made to work in individual countries. • There was discussion regarding France. There are laws in place that are more demanding than EFPIA’s code and France is something of an exception. There is a huge overlap between Loi Bertrand in France and EFPIAs requirements – there is duplication if members are going to meet the rules of being an EFPIA and national association member and meet the demands of the law. Need to check that currently the pharmaceutical industry association didn’t publish anything in relation to Loi Bertrand. If there is an exception to be made for EFPIA’s disclosure requirements in France because of existing laws in France, CM will let EphMRA know. It was CM’s understanding local laws would be the one to be followed in priority to EFPIA and she will check this out and advise the Committee • PR to look into disclosure gaps in Italy. • PR was concerned with the lack of time in 2015 to focus on research due to expanding compliance requirements and asked what support can EphMRA offer? France have to do Loi Bertrand which is already a demanding process and on top of this EFPIA. In Italy it is unclear about asking permission for physicians to take part in the research and the time and effort taken to get an answer, positive or not. • Can we find an agreement, a way to make sure if a physician is asking for a permission that it is valid for 12 months for instance and then we’re more than happy to publish their name and whatever incentive we pay to them? • It was said that there is some good news in there when you look carefully at the EFPIA requirements, disclosure is only necessary when first of all an incentive has been paid and the identity of the HCP is known to the commissioning pharmaceutical company. EphMRA did lobby quite hard for that provision. EphMRA did do some significant work with EFPIA trying to explain to them what market research was and the definition of market research that now appears in EFPIA’s documentation is EphMRA’s words. So there is some impact there and we are somewhat relieved that disclosure is only in limited circumstances for market research that we have. • The biggest threat that this disclosure requirement offers is really to pharmaceutical companies that want to do a bit of their own market research. • PR acknowledged this effort and achievement. However, it is still becoming too much, AER, reconciliation at the end of the project, call the physician to get the permission for reporting and then there is the EFPIA requirements influencing a limited amount of physicians. Most agencies are small to medium size and are struggling with all these activities. • CA reminded everyone that for first time there is a public affairs plan and late last year time and effort was spent in identifying priority organisations
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		<p>and territories with whom we should try and build relationships, either building on what we've already got or starting from afresh. Goals are short, medium and long term to work with those organisations. It's a significant priority for Georgina and Ian as the new chairs and it's also taking an increasing amount of Bernadette's time but it does no harm to be reminded just how important it is for those of you on the ground.</p> <ul style="list-style-type: none"> • BR suggested that it probably needs to be raised again at Board level, so shall put this it into Georgina's report and see what their views are. • This subject will be added to the agenda for next meeting and how we want to take this forward in terms of public affairs. There is an increasing burden on the industry and our clients.
	<p>Next Meeting</p>	<p>TBC - April 2015</p>

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