

Present	BB	Bettina Brust
	BD	Bob Douglas
	BR/GM	Bernadette Rogers - General Manager
	BR	Beatrice Redi
	CA	Catherine Ayland
	GB	Georgina Butcher
	IM	Ignacio Macías
	JB	Jeremy Brody
Apologies	HeF	Henri Farina
	KG	Kim Gray
	PR	Piergiorgio Rossi

UPDATE & ACTIONS

1. Code of Conduct Update

- a. Social Media Guidelines – included in the Code from Dec 2011
 - Query on the definition of social media discussed, CA to document response and circulate CA
- b. Extensions update
 - Poland) Review of CofC underway locally, first draft to be
 - Russia) complete end March 2012, goal is to finalise in time to
 - Turkey) include in mid-year re-print for release at Conference
 - Japan) CA to integrate CA
 - China)
 - India) BR to updated – discussions ongoing, slow but sound progress
 - Korea)
- c. Future developments in Code content:
 - Discussions with Information Commissioners Office and ESOMAR with regard to interpretation of Data Protection requirement to name receiving company when non-anonymised recordings of fieldwork are made available to the client company are ongoing
 - New pro forma for a video-streaming respondent agreement – on hold until further clarity on legal responsibilities described above
- d. Next update scheduled – quarter 2 2012

2. News/developments in Ethics Group territories

- France – confusion with regard to interpretation of legislation that may have implications for the recruitment of patients via patient associations is under investigation
- Germany – confusion arising from German legislation with regard to the status of patient record studies was discussed, EphMRA response to be sent to JB by CA CA

- Further develop and clarify the definition of 'non-interventional studies' distinguishing them clearly from market research CA
- USA – Update on US State Law Summaries to be provided by KG KG

3. Moving to mandatory (rather than discretionary) Code of Conduct – Next Steps

- Closing date for feedback was end January 2012
- Next steps:
 - Analysis of member feedback CA/BR/BD
 - Update at IMM 7 Feb 2012 by GB & PR
 - Feedback to members on issues raised
 - Discussion with Ethics Steering Group and Ethics Group
 - Member vote (online via EphMRA website) – timing tbc
 - Announce results and any further plan at June 2012 AMM

4. Code of Conduct Enquiries

- Update - 83 enquiries in total, 59 in the last 12 months, averaging about 5/month
 - Of all enquiries - 63 agency enquiries, 20 pharma' company enquiries
 - Wide variety of subjects – data protection, patient diaries, AER, informed consent at recruitment and for recording, use of lists, use of social media, testing promotional material/products/devices, video-streaming, client company interviews, incentive rates.
 - Plus 17 email only enquiries (5 pharma company enquiries)

5. Training

- a. 2012 Ethics Training Workshop – Half day *What's New* workshop to take place 19 June in Paris immediately before AMM and Conference, to include:
 - Implications of pharmacovigilance legislation for AER
 - Social media MR guidelines
 - Guidelines for client company access to fieldwork
 - Privacy and data protection developments
- b. Feedback from 24 January Webinar – *Ethics on the Fieldwork Frontline*
 - 100+ registrations for the webinar – 70:30 AMs:FM
 - Wide range of FMs – UCB, AZ, Bayer, Merck, Sanofi, Merz, Novartis, Abbott, Allergan, Shire, Daiichi, Pfizer
 - Series of questions (36)
- c. Update on online training progress
 - 106 completed
 - Update of online content completed and uploaded
- d. In-house Training
 - Training for UK based agency (10 staff) to be undertaken 10 February 2012
 - Webinar for Medical Staff reviewing MR materials/stimulus under discussion with FM
- e. Content of Competency Test has been updated, uploaded on to website on 9 Feb 2012
- f. Update on Competency Test/Certification take-up
 - 312 individuals have take the Competency Test to date
 - BR to conduct an analysis of the type of individuals and organisations taking the test BR

6. Beijing Conference – Ethics Content

- Panel discussion and Q&A session proposed

7. New pharmacovigilance legislation and implications for Adverse Event Reporting

- No further communications from EC or EMEA and no responses available online yet

8. AER Foundation Project Update

- BD updated, no comments

9. Ethics Group Membership

Comment from full member:

If the EphMRA Code of Conduct is decided by the EphMRA Ethics group I think it makes sense to allow EphMRA member to vote for who is in that Ethics group, to at least have indirect influence.

This issue is to be tabled for the Executive Board

BR