Ethics Steering Group Minutes – 15 March 2012

On call: Bob Douglas, Georgina Butcher, Piergiorgio Rossi, Catherine Ayland, Bernadette Rogers

Bob summarised that a call with the MRS had demonstrated that if we move to a mandatory code status then EphMRA will require significantly more resources in place which will mean greater investment. The timeline for a proposed vote by the AGM will not take place as first envisaged due to the amount of preparation and advance work needed and the possible implications. There could also be some risks in terms of membership – whilst AMs were generally positive and clearly in favour the FMs, although positive, expressed some concerns about legal issues, authority to sign etc.

It was agreed at the Board meeting that a White Paper will be written and made available by June to the membership and this will give as much information as possible to members so that they are fully informed about what might be involved. The possible cost of the resources needed to support the move to a mandatory Code will be assessed.

This White Paper will be structured as follows:

1. Scope of the Code of Conduct
2. Adverse Event Reporting
3. Accuracy of the Code of Conduct
4. Consultation upon Code changes
5. Legal consequences and liabilities
6. Insurance
7. Enquiries
8. Membership
9. Grievance
10. Training & Competency Testing

Code Scope

There was discussion as to whether we can continue to support the very comprehensive and detailed Code that we have. When first developed there was a need to a more detailed and specific Code than the previous version which was lightweight. To maintain a large and very detailed code is indeed a demanding and intense job. Country differences could be put in an Appendix? However many members appreciate the detail which the Code contains – the fact that it give specific information and guidance.

If members were being asked to sign up to the Code would it make it easier if the core Code was leaner and less detailed?

The Code could be examined to see which are the 'musts' and which are the 'shoulds' – this could help to focus on the elements of the Code which are legally binding. The Code is built to protect respondents and to ensure we work to a high standard. The law can be interpreted in different ways and based on the law EphMRA has drawn up its Code to give best practice.

The Code will be reviewed by Catherine - the 'musts' to ensure we are not being over zealous and then the Ethics Group will look it over. The next step will be to have it legally reviewed to ensure that the terminology is clear and all is legally aligned. The third step could be to ask 2-3 pharma companies to have their legal departments review the Code see if they can envisage any problems if they were asked to accept it as a mandatory Code.

Grievance Process

The MRS and ESOMAR processes are described in this document. The EphMRA emphasis will be on trying to resolve the issue before escalation and ensuring members can find appropriate solutions. Publication of a breach of the Code should be a very last resort and this should be avoided.

There was discussion as to whether the number of complaints will increase once the Code is mandatory. What sort of complaints will we get and on what topics? Many pharma companies can address issues through their MSAs. EphMRA will need to determine if it is to address complaints which are commercial in nature – especially if the issue could bring the industry into disrepute. EphMRA may need to address some commercial issues between suppliers if necessary – TBC.

It is clear that a majority of 'complaints' can be cleared up quickly through emails and telephone calls – they could be mis-understandings or based on commercial complaints which are outside the Code. ESOMAR do attend to resolve these informally if they believe the activity is damaging to the industry etc.

EphMRA will need a Grievance Group/Committee comprised Full and Associate members (if possible) to review cases, this will be done on a volunteer basis and the work could be divided into small sub-groups. Applications to serve on this will be sought from the membership and will be appointed by the Board. This Group need to be independent.

A legal adviser will be needed to support this work.

All grievances need to be submitted in writing naming all involved parties, there must be clear documentation.

The MRS and ESOMAR will be asked about the type of complaints they receive and what type they actually investigate.

TC with MRS & EphMRA Ethics Steering Group

14 March 2012, 10.00 - 11.00

EphMRA Code of Conduct Move to Mandatory Adoption

Present:

EphMRA	Bernadette Rogers
	Bob Douglas
	Catherine Ayland
MRS	Debrah Harding – Chief Operating Officer
	Barry Ryan – Standards & Policy Manager

Background

MRS had Code since 1954 always been binding on members but major changes made mid-2000s:

- 2005/06 – Code extend to companies rather than individual members – company partners
- Govt. had indicated that individual membership status was not adequate and that heavier weight regulation was required
- Introduced contractual arrangement with company members
- Company partners have a contractual organisation that cascades down through the company
- MRS Quality Commitment that includes following the Code, signed by the MRS and company. It is a very brief simple document to smooth its passage, also includes signing up to the complaints procedure.
- Described as a 'standards based scheme' offering incentives in the form of a series of discounts (benefits/value for the companies)
- Company partners do include large multi-nationals –but membership may be limited to specific depts., it depended on how far the company felt able to sign up
- There is a link to individual membership too – 1 individual member per company
- Seen by some as a fairer way to be regulated i.e. through the company rather than through the individual.
- Company partners must pass on their obligations to their sub-contractors
- When launched the MRS put effort into letting buyers of research the benefits of buying from regulated suppliers.

MRS Code

The Code must stand up to legal scrutiny (has to stand up in court) – has to be enforceable.

Current MRS Code is a mix of principles and in places prescriptive.

MRS Code may be a minimum standard in the light of other more stringent requirements.

Traditionally members have wanted to work with members - this still persists.

Complaints process

25 cases a year that go through investigation, 3 or 4 cases a year will be large-scale investigations, every other year a huge case comes up.

Companies have very deep pockets – will wield considerable legal and financial clout.

Company partner Complaints Process would be relevant to EphMRA:

- Receive complaint (cannot be anonymous)
- MRS will look into it (many are resolved at this stage)
- 15 member board MR Standards Board
    - Sub-committee of 3 of 15 will investigate
    - Conclusion is communicated to complainant
    - Recommendation to full board
    - Full board review and decide
    - Finding published
    - Complainant can ask for review if complaint is not upheld, may be referred back for investigation
    - Can take 3 to 6 months but may well take longer.

There may well be a peak in the early years as the process settles in.

Occasionally individual members are expelled (generally on the basis of fraud/dishonesty).

No partner company has had their contract terminated.

Publication of judgements is greatest effective punishment and deterrent.

Suggestion from MRS - Can there be sharing of tribune personnel?

Insurance

Get insurance! Insurance is not massively expensive and covers all those involved but there are risks, mistakes made by the MRS in the complaints process would invalidate the insurance.

Reactions

Overall good but the value package is tailored to individual company requirements.

Overall seen as positive but there will always be pressure/conflict between company and individual needs.

Training

No mandatory requirements for training but do have:

- Quarterly standards briefings – updates and issue specific
- Codeline advisory service.

Introducing changes to the Code

12 month minimum process to update Code (3 months consultation).

Plus 6 months on the road explaining the Code, road-shows and company partner visits.

3 to 4 year cycle of reviewing the Code which then has to be cascaded through to guidelines.

Time split – over different areas of responsibility

Code development) 15%

Education)

CodeLine – everyday 50%

Complaints – 35%

Standards board members – average 2 days/month for meetings and reading but large cases may need more support

Jurisdiction

Depending where EphMRA offices are registered there are procedural requirements associated with the country under whose jurisdiction the organisation comes – members would have to be made aware of this

Ethics Steering Group Minutes - 22 February 2012

On call: Bob Douglas, Georgina Butcher, Catherine Ayland, Bernadette Rogers

Apologies: Piergiorgio Rossi

1. **Feedback on making the Code Mandatory**

Overall the feedback received was very good.

In general fieldwork agencies were in favour of the move to a mandatory code.

Full Members seemed a little more reserved - expressing concerns that this move might negatively impact on their membership of EphMRA. Caution is advised as we don't want to alienate the membership. Some companies do not perceive a clear benefit in terms of a mandatory code and were worried about how it might work in practice.

A difficulty for many pharma companies is that departments as well as market research also commission market research and so this could cause some concern as it could be difficult to internally manage adherence to the code.

Two main issues:

1. How would a mandatory EphMRA Code would fit with a pharma company's own internal Code.
2. Who on behalf of the pharma company has the authority to sign to accept a mandatory Code?

With regards to any conflict between the Code and local laws it does currently state in the Code that local laws take precedence but maybe this needs to be more clearly emphasised. We may need to extract country differences into an Appendix and highlight them.

There are 2 other important issues to evaluate:

- We have to undertake some work to polish up the Code
- We would need communications and PR to explain the issues

But these are not perceived to be major barriers and can be overcome.

2. **AER**

AER could be an area of potential conflict if minimum standards outlined in a pharma company's Code were different to those of EphMRA. In our Code maybe we should state that this is EphMRA's

view on AER and is a minimum standard and pharma companies may have different standards – often they are more stringent.

3. Testing & Training

The BHBIA – here it is individuals who undertake the training and testing – anyone listed as a main company contact must be certified and these persons are then responsible for ensuring the company is compliant.

It was decided to leave training and testing as a voluntary aspect whether the Code is mandatory or not. This was felt to be better for the membership as we do not want members to feel burdened by repetitive testing and certification.

However there could be a case for streamlining the UK testing. BHBIA will be contacted to ask if they would like to have an exploratory conversation about the principle of having one test or streamlining the testing.

4. Insurance

Is insurance needed for EphMRA? Who is liable – the company or individual - who is responsible?

5. Maintaining the Code

How to keep the Code up to date is a future consideration. Keeping track of changes etc is a considerable task. With a move to a mandatory code we would need to be much clearer on how the code fits with local guidelines – and keep more up to date with local changes – maybe having a clearer process in place. Who agrees changes to the Code needs to be determined more clearly.

The Code may need review in order to check through terminology and be consistent and clear.

6. Legal Counsel

It was felt that we should have a legal adviser on board acting as a consultant for when we need expert advice.

Barry Ryan of the MRS is a lawyer and also has a European role. The MRS also make use of a firm of lawyers.

7. Grievance process

This needs to be looked at and assessed as to what is involved and what issues EphMRA would deal with. ESOMAR have clear guidelines as to what they deal with and this has been included in these minutes.

8. Ethics Group Structure

It should be discussed as to whether the EG should be restructured – possibly a more international researchers ethics group is needed with local country ethics experts as a sub group – this needs further consideration and assessment in the light of what our future ethics structure might be.

9. Action Points:

Catherine: To compile a list of issues as a basis for a feedback structure to members – this is included in these minutes.

Bernadette: to discuss more with ESOMAR – the feedback so far is also included.

Bernadette: to contact BHBIA – as yet not done.

ESOMAR PROCESS

The ESOMAR Professional Standards Committee (PSC) examines complaints lodged against ESOMAR members in relation to possible breaches of the ICC/ESOMAR International Code.

ESOMAR members are individuals that have undersigned to abide by the ICC/ESOMAR International Code and ESOMAR's disciplinary procedures. All ESOMAR members are subject to the disciplinary process.

All complaints must relate to the actions of an ESOMAR member, i.e. complaints regarding projects that an ESOMAR member is responsible for, or for the staff involved. Please use the members search to see if an individual is an ESOMAR member.

All complaints must be supported by documented evidence. The disciplinary procedures allow ESOMAR to impose sanctions if the member is found to be in breach of the ICC/ESOMAR International Code. Sanctions range from private warnings, to expulsion from membership and publication of the sanction imposed on the member.

There are some issues that the disciplinary procedures do not cover. Examples include:

- Complaints about someone who is not an ESOMAR member and is therefore not subject to the disciplinary procedures. However, in exceptional circumstances, ESOMAR may take specific action to protect members, the reputation of market research or of ESOMAR. Please use the members search to see if an individual is an ESOMAR member.
- Legal issues such as contractual, payment and employment issues which are better dealt with through commercial or legal means. Action may be considered, however, in circumstances where the activities surrounding these issues appear to establish a pattern of behaviour by a member that may damage the reputation of the market research profession.
- National complaints that would normally be dealt with by the national association. ESOMAR may respond if there is no national association or the national association cannot handle the complaint and asks ESOMAR to assist. Please use the associations search to find the contact details of your national association.
- If you are unsure whether the ESOMAR disciplinary procedures cover your complaint, please send your query to professional.standards@esomar.org for review.

Please note that complaints will be assessed against the ICC/ESOMAR International Code and must be supported by evidence.

Before making a complaint please refer to the ICC/ESOMAR International Code, the related Notes and to the disciplinary procedures.

ESOMAR also publishes guidelines on specific subjects, such as online research which are based on the key fundamentals of our Code. Please go to the Codes & guidelines section to review our guidelines.

Download a copy of the complaint form.

Final checklist:

- Have you checked if your complaint is about an ESOMAR member?
- Have you provided a brief summary of your complaint and which article of the ICC/ESOMAR International Code you believe the member has breached?
- Have you included copies of relevant documentation as evidence supporting your complaint (e.g. any previous correspondence, research proposals etc)?
- Before lodging a formal complaint, please note that you may contact us for informal assistance or with queries at: professional.standards@esomar.org.

The ESOMAR Process

ESOMAR have around 25 ‘complaints’ a year – most are quickly sorted and don’t go beyond a couple of telephone calls or emails.

About 3-4 a year are investigated. Sometimes ESOMAR will investigate commercial complaint ie a company repeatedly not paying invoices as this brings the industry into disrepute and they want to iron it out.

The complaint passes through the Professional Standards Committee (who initially assess if there is a case to look into) and onto the Disciplinary Committee (DC) – both are entirely separate and have no overlap or communication (no bias). The DC is headed by a senior Dutch lawyer and is comprised experienced international researchers/a couple of past ESOMAR Presidents.

Insurance – Directors Liability Insurance is in place – we need to look into how this works – at ESOMAR I think it is the Council members who are insured (but needs clarification).

As ESOMAR have both individual membership and company membership the company liability is based on 'legal jurisdiction' ie a company registration number or VAT number – there is no worldwide membership – has to be on an operating unit basis.

ESOMAR have a freelance lawyer who works in Holland – he is an expert in European:

1. Privacy
2. Telecommunications Law
3. Internet Law
4. Data Privacy
5. Intellectual Property
6. Compliance
7. Privacy Law
8. Personal Data Protection
9. Consumer Law
10. Advertising Law

ESOMAR say they can share his contact details if we are interested and we could approach him to see if he would like to work for us. ESOMAR only pay on fee for work basis – no retainer.

ESOMAR also offered to share (on a cost basis) use of their Disciplinary Committee provided we can supply a couple of healthcare MR experts to serve on it.

EphMRA Code of Conduct - Consideration of the Move to Mandatory Adoption

Prepared by Catherine on 27 February

Key issues raised within the feedback by EphMRA members (not listed in any particular order):

Scope of the Code of Conduct

- Code of Conduct Vs national legislation and guidelines Vs Client's own guidelines/rules
- Geographies covered and 'jurisdiction' in non-Code covered countries
- Would we have to revise the line taken - reduce the minimum standard?

Accuracy of the Code of Conduct

- Keeping up to date with change – national, international, codes, guidelines, legislation
- Clarity essential
- Accuracy and ambiguity are concerns
- Accuracy of translations

Consultation upon Code changes

- Will a mechanism for consultation upon Code changes be required and put into place?

Legal consequences and liabilities

- Consequences) for EphMRA
- Liabilities) and members
- Legal support required

Insurance

- What would be required, for what, by whom and at what cost?

Enquiries

- Speed of response to enquiries
- Might legal checking of responses be required?

Membership

- Company or individual?
- Working relationships with non-member companies
  - Liability and the chain of sub-contractors

- Would EphMRA lose members?

Monitoring/policing/complaints/grievance/disciplinary procedures and measures

- Requirements
- Legal implications
- Financial implications
- Communication/publication of breaches

Training & Competency Testing

- The status of training – mandatory or discretionary
- Similarly the status of Competency testing – mandatory or discretionary
- The overlap between BHBIA and EphMRA testing
- Scope of training and testing required
    - Market researchers Vs non-market researchers
    - All market researchers Vs nominated company representatives alone

Adverse Event Reporting

- Updating of current guidelines