

## EphMRA Code of Conduct: The Q&A

If ever you need clarification on any aspect of the EphMRA Code of Conduct, don't hesitate to use our Code Query Service.

Many members have already done just that – and here, for the benefit for all, are some of the anonymised questions and EphMRA's answers.

### Q&A Categories

1. **ADVERSE EVENT REPORTING**
2. **DATA PROTECTION**
3. **ONLINE RESEARCH**
4. **VIDEOSTREAMING**
5. **PRODUCT TESTING**
6. **CERTIFICATION**
7. **USE OF PRODUCT NAME IN MARKET RESEARCH**

### 1. **ADVERSE EVENT REPORTING**

#### 1.1 The Enquiry was:

I'm currently doing some work on the convenience of a vaccination syringe. If we survey patients about their vaccination experience, how do we deal with reports of injection pain/discomfort?

Would such pain be classified as 'unwanted and undesirable' and therefore need to be reported and investigated? Could you advise before we embark on such a study with patients?

#### EphMRA's Response is:

EphMRA's Adverse Event Reporting Guidelines do not make any direct reference to reporting of adverse events associated with medical devices not to the discomfort or pain that might be associated with injections. Neither is there a definition of 'unwanted and undesirable' events.

In these circumstances EphMRA recommends that you contact the company you are contracted to work with in order to define the requirements for collection of device related reports in line with Article 10 of Directive 93/42/EEC. EphMRA would strongly advise that the drug safety/pharmaco-vigilance department/team at the client company is consulted for guidance on this issue.

EphMRA does say within its Q & A advice that:

*"It is our view that great care should be taken when preparing a questionnaire so as not to bias any responses provided. If questionnaires are prepared in such a*

*way that they try to avoid asking questions that might give rise to an AE, this might result in an unbalanced set of answers and not provide clients with appropriate "balance" they would normally expect from MR investigations. "The tail should not be allowed to wag the dog."*

## 1.2 The Enquiry was:

We are currently discussing with various clients the opportunities to gain information from the social media. You can imagine that we have been asked very often how we deal with the issue if an adverse event is described (which happens more often than in conventional market research studies). Your point of view is so far that we do not have to report because

- we do not know the physician or patient who reports and therefore we can not go back to him / her
- in most cases it is totally anonymous
- the adverse event is described more " abstract" (" ..... I have some patients who get headaches after having used product X"!)

## EphMRA's Response is:

Adverse events (AE) cited within a market research study that meet the reporting criteria must be reported – irrespective of the medium. So those that arise during the course of market research using digital media should be reported if they meet the reporting criteria.

There are four minimum reporting criteria and each must be present to make an event eligible for reporting:

1. An identifiable patient - identified by initials, number, date of birth, age, age group or sex, only one of these identifiers is required to ensure the patient is identifiable.
2. An identifiable reporter - the reporter may be identified by name/initials and address or qualification (e.g. doctor, nurse, patient, pharmacist).
3. At least one suspected adverse event.
4. At least one suspected active substance/medicinal product.

If one or more of these four key pieces of information is missing, the event is not 'reportable' and it is not the researcher's responsibility to probe or prompt for the missing information. So if there is no identifiable reporter, the AE does not meet the reporting criteria and need not be reported. If there is no identifiable patient, the event does not need to be reported. However if the four key criteria are mentioned then the researcher should prompt the reporting of the event.

Please note that in the UK, pharmaceutical companies and their legal agents must now forward all adverse events that are cited in the context of any patient or

December 2010

patients, whether or not a specific identifier is present. Previously a specific identifier was required. So if a physician said "I have some patients who get headaches after having used product X", this is deemed reportable in the UK, according to the ABPI new Guidelines. However not all pharmaceutical companies are adopting the ABPI's Guidelines in full, so it is recommended that the commissioning company's internal policy on AE reporting is consulted. For further details upon the UK AE Reporting Guidelines see: <http://www.bhbia.org.uk/Library/ABPIAdverseEventGuidelines/tabid/323/Default.aspx>

### 1.3 The Enquiry was:

We are doing a multi-country study one of which countries is Germany. The UK based analyst has found an AE during one of the interviews but we are unsure as to whether this needs to be reported. It was an interview with a patient and this isn't specifically mentioned in the CoC. It says that patients should be told at the end of the interview to report it to their physician and it says German physicians should be told to report it to the company.

However, neither of these are 100% relevant and this has only be raised (as far as we are aware) at the time of analysis. Please could you let me know what further steps need to be taken?

### EphMRA's Response is:

EphMRA's Adverse Event Reporting (AER) Guidelines do not include conditions attached to the reporting back of adverse events (AE) to pharmaceutical companies. The Guidelines go only as far as saying that respondents that raise a reportable AE should inform their physician or the pharmaceutical company.

It is understood that in some circumstances the adverse event can't be reported at the time fieldwork take place e.g. where there is no interviewer present or there is an oversight – as in this case. In these instances EphMRA advises that the client is advised of the adverse event as soon as reasonably practical and ideally within 24 hours of it being identified. The client company's drug safety department should then advise on any action to be taken

### 1.4 The Enquiry was:

According to the BHBA, forwarding Adverse Events now applies to syndicated/multi-client studies in the UK.

I would be grateful if you could tell me what the situation is in Germany, France, Italy and Spain. What do the guidelines of the healthcare association of each of these countries state about adverse events and syndicated studies?

EphMRA's Response is:

In the UK, the ABPI's Guidelines for Collecting Adverse Events and Product Quality Complaints from Market Research Programmes state:

3.4 Patient Level Diary Studies

For syndicated patient level diary studies there is no obligation on the supplier to report AE/PC contained within the diaries to Marketing Authorisation Holders.

Where individual patient records, containing all the relevant fields for an AE/PC, are purchased by the MAH from a syndicated patient level diary study, then there is a responsibility on the MAH to process any individual AE/PC reports contained within these records.

Wherever syndicated patient level diary data are only purchased at aggregate level, there is no obligation on the MAH to request the underlying individual patient data.

Prospective patient level diary studies conducted for an individual company are considered as ad hoc research and follow the guidelines for primary ad-hoc research.

These Guidelines were revised in November 2009 and are effective in the UK for any market research study commissioned from 1<sup>st</sup> May 2010.

Consequently the UK BHBA's Guidelines state that:

For syndicated studies e.g. patient diary studies, **there is no legal responsibility for the supplier to forward AEs** because the supplier is not the legal agent at the time of data collection.

**The legal responsibility to collect AEs lies with the pharma company that purchases the syndicated data.** The pharma company market researcher should forward the AE data to their PV department. **The supplier may be requested to prepare patient record data in the appropriate format for the pharma company client.**

The company researcher should forward any AE data whether individual patient records or aggregate patient data are purchased.

Ad hoc studies that collect actual patient data should be treated the same way as all other ad hoc primary market research i.e. the contracted supplier must forward any patient records that contain AEs to the pharma company within one business day of first becoming aware of the event.

The situation in Germany, France, Italy and Spain remains unchanged with regard to EphMRA's Guidelines on Adverse Event reporting for syndicated data – see page 21 of EphMRA's Code of Conduct:

*Adverse Event Reporting – Syndicated and Audit Data*

13.2 *In those cases where a market research agency is conducting a syndicated investigation on its own initiative, and is offering the data to any potential pharmaceutical company, as the market research agency is not under any legal obligation to provide details of adverse events to the medical authorities, no adverse event reporting is required.*

*If client specific confidential questions are incorporated into these types of investigations and these lead to an adverse event being mentioned, then the same procedures mentioned at 13.34 for custom market research apply.*

*If one or more pharmaceutical companies collectively request that a market research agency conduct a 'shared confidential study' for them on an exclusive basis, then the same rules for custom market research apply.*

*If data, especially diary data is being examined on an aggregate basis then no reporting by pharmaceutical companies or market research agencies is required. If the pharmaceutical company requests patient specific data then the company will need to report any adverse events that are identified **except in the UK**, revised UK Guidelines now require the company to forward adverse event data whether individual patient records or aggregate data are purchased.*

*With regard to any other audit undertaken by a market research agency if the data collected is able to be purchased by any pharmaceutical company, then as the market research agency is not itself a pharmaceutical company it is not governed by any reporting rules to medical agencies involved in pharmaco-vigilance. Consequently it is not necessary to prepare any adverse event reports at this time.*

## 2. DATA PROTECTION

### 2.1 The Enquiry was:

"Recorded data (audio or video) given to clients without respondent permission must be anonymised. It is recognised that audio/video tapes may be difficult to anonymise as an individual's voice/appearance/turn of phrase/opinion may be identifiable, particularly in specialised healthcare fields where the respondent universe is small. In Germany if the recording identifies the respondent it cannot be given to the client even if permission was granted."

Can you further define 'identifies the respondent' in the German context? Does this mean that, even with informed consent releases, we cannot show ANY footage of German patients to our client? Is blurring faces and deleting any other identifying information adequate anonymisation in this instance?

### EphMRA's Response is:

In Germany identifiable (personal) data must not be given – in any form or context – to the commissioning company. Consequently, the respondent's identity must be completely disguised to ensure that the data is anonymous before it can be passed to the client. In Germany obtaining a respondent's explicit informed consent to pass on personal data cannot override this regulation. This means for instance, that images must be pixilated to hide the respondent's identity on video recordings before they can be shown to the client. In addition if there is any chance that voices could be recognised these must be disguised or dubbed.

*'Key problems in the Data Protection Laws and Professional Laws for Scientific Survey Research'* issued by the ADM (Germany's market and social research industry body) states that:

Clients of market and social research, particularly those coming from countries in which other data protection regulations apply, sometimes demand that respondents should be given the opportunity of deciding for themselves, whether their data should be anonymised or whether they may be passed on in a personalised form. They justify this demand by pointing out that the German Data Protection Act does allow for such permission, expressing the view that there is no reason to be stricter than required by the data protection regulations. For several reasons, this demand must be rejected without exception, as must all such practices. They contravene both the Federal Data Protection Act (see Item 4) – despite the possibility of obtaining permission allowed for there – and the professional laws of market and social research, as dictated by the professional rules of the Arbeitskreis Deutscher Marktund Sozialforschungsinstitute e.V. (ADM) and the erufsverband Deutscher Marktund Sozialforscher e.V. (BVM) and the declaration by these associations regarding the ICC/ESOMAR Code of Practice.

## 2.2 The Enquiry was:

I am working on a proposal for a client and it involves their end client conducting the interviews. Is that something we are allowed to do in the UK? If yes, what are the procedures or any considerations involved? We know for a fact that Germany is not allowed.

## EphMRA's Response is:

Client company market researchers are allowed to interview respondents directly in the UK but are not allowed to do this in Germany.

**The British Healthcare Business Intelligence Association's (BHBIA) Legal and Ethical Guidelines state that:**

### **8e Company Involvement in Recruitment**

- 8.1 *Companies can recruit and field their own market research studies. All of the conditions that apply to agency-led studies apply to company-run studies too.*
- 8.2 *As the company conducting the market research is the sponsoring company, the sponsor's name must be revealed as the respondent must be made aware of the name of the organisation for which the interviewer is working.*
- 8.3 *Respondents' personal details must remain confidential and inaccessible to anyone outside of the market research team or unit.*

**In Germany federal data protection legislation forbids the client access to respondent data (EphMRA Code of Conduct 9.3). Whilst in other countries the respondent can waive their right to confidentiality, federal data protection legislation will not allow this in Germany (9.4).**

**If further information is required please see:**

*ADM Key Problems in the Data Protection Laws and Professional Laws for Scientific Survey Research [www.adm-ev.de/pdf/Kernprobleme\\_E.pdf](http://www.adm-ev.de/pdf/Kernprobleme_E.pdf) Aug 2009*

### 2.3 The Enquiry was:

I have had a query from a US client as they have heard of new guidelines I was not aware of and want to check if this is correct. Their query is: "if there may be new EU regulations in place that require individual patient approval if study data on these patients are going to be analyzed outside the EU."

This is anonymous data collected from patient records or patient chart audit studies. I think my client may be confusing with the identifiable personal data.

Can you please confirm any guidelines around sending patient data from the EU outside of the EU for analysis and review.

### EphMRA's Response is:

There are no new EU regulations that EphMRA is aware of that require individual patient approval if study data are analysed outside the EU, whether or not the data is identifiable or not.

The regulations currently state that personal data collected within the EU is protected by the provisions of the Data Protection Directive/Safe Harbor Principles even when taken out of the country where the respondent lives.

In addition the transfer of personal data to non-EU/ countries is forbidden unless there is adequate privacy protection in place.

Once all identifiers linking data to a respondent have been removed then it no longer constitutes personal data and is not covered by the Data Protection Directive/Safe Harbor Principles. It is permissible to use a unique identifier (e.g. a serial number) to identify a respondent but the file linking personal data to the unique identifier must be stored entirely separately from the anonymised respondent data.

If you require any further information please see Section 6, Data Protection and Privacy within EphMRA's Code of Conduct.

## 2.4 The Enquiry was:

We have a patient study where the respondent films their daily life with their condition. This is being conducted in a number of countries. There have been concerns that for fieldwork conducted in Germany we will not be able to pass the recordings to the client. Can you clarify the following?

Can we pass these recordings to the client if we obtain signed informed consent from the respondent?

Can we include clips from these recordings in our presentation if we obtain signed informed consent from the respondent?

## EphMRA's Response is:

Recordings (audio or video) that identify the respondent cannot be passed to or shown to the client even if a respondent has given their permission. In Germany personal data (any data that identifies the individual) cannot under any circumstances be passed to the client, there are no exceptions or waivers allowed.

*ADM Key Problems in the Data Protection Laws and Professional Laws for Scientific Survey Research [www.adm-ev.de/pdf/Kernprobleme\\_E.pdf](http://www.adm-ev.de/pdf/Kernprobleme_E.pdf) Aug 2009*

## 2.5 The Enquiry was:

1. All MR companies need to have a designated data controller (the one who hold and in charge of the privacy of the database of personal information), and need to register with ICO.
  - a. Where can I found such requirement documented?
2. Personal data can be passed between agencies if there is a confidential/anonymity agreement between the agencies.
  - a. Where can I found the specific clause on this matter
  - b. How should this confidential/anonymity agreement be drafted?
  - c. Under what condition can we do this and not? Like a client of ours ask for personal details from the respondent, and they send us a signed confidential/anonymity agreement, and we can release the information immediately afterwards?
3. Respondents' consent of passing personal data to another party is NOT allowed after fieldwork. We have a large panel which we know our panellists' name, address, email, all personal details. Some clients of ours did not mention they want to collect some personal information, e.g. postcode, for analysis purpose at the beginning/recruitment stage of the stage. This is often requested AFTER fieldwork is finished. One of the comprise we can offer is to ask these respondents whether they agree to pass their postcode, hospital name or others to client ABC. They are our panel members, so they

gave consent to us to contact them multiple times for all MR related questions.

- a. Is this true that this action of contacting respondents AFTER fieldwork is NOT allowed?
- b. If so, please advise the specific clause in the Code of Conduct. Because we are asked this very often to do this.

EphMRA's Response is:

- 1a The website of The Office of the Information Commissioner is the best source of information - [www.ico.gov.uk](http://www.ico.gov.uk) – within the 'For organisations' section there is advice on 'Notification'.
- 2a See page 11, points 11.4 and 11.5 of draft 6.3 (6 Sept 2010) of the Code of Conduct – available online only on the EphMRA website.

*When studies are conducted that draw respondents from a list supplied by an agency, recruiter or the client company, the list provider must ensure that the list conforms to local data protection and privacy legislation.*

*Lists that are drawn from sources within the public domain do not generally require the permission of the individuals listed to have their personal details held (all of the data must be drawn from the public domain). So if for instance a list of healthcare professionals (HCPs) was drawn up from health centre websites that listed the HCPs working there, this would not require the HCPs prior consent, and if these details are passed to another party and that party is contractually designated the 'data processor' (the list holder being the data controller), then again, the permission of the individual need not be sought. Similarly if a list of detailed physicians was passed to a market research agency to allow them to draw a sample from it, as long as the agency had been contractually designated the data processor (the client company being the data controller) this does not constitute the 'transfer' of personal data and does not require the permission of the listed individuals.*

*If however local law/regulations demand that the explicit permission of those on the list is required before their personal details are passed on as **in Italy**, this must be complied with. **In Italy**, data that is used that is not publicly available should be 'certifiable' – those that hold the data must have the consent of the individual and evidence of how they obtained the data. It is also strongly recommended by EphMRA that the responsibilities of list suppliers are made explicit and agreed to in writing within some form of project agreement, such as the contract.*

*It should also be remembered that:*

- *Those included on a list must be told of the purpose of the list when giving consent for the inclusion of their personal data*

December 2010

- *The client company must not be informed of the identity of market research participants, i.e. who on the list was interviewed.*

2b As stated above it is a contract that details the contractual relationship between vendor and supplier not a confidentiality agreement. EphMRA do not provide advice on the content of contracts.

2c & 3 Personal data cannot be supplied to the client unless the respondent has waived their right to confidentiality and has provided their explicit written consent. Retrospective consent is not adequate. Market research respondents including panel members must be asked at recruitment if they will provide permission for their personal data to be forwarded to a client.

See points 4.1, 6.2, 6.3, 9.3, 9.4, 11.7 and 11.9 of draft 6.3 (6 Sept 2010) of the Code of Conduct – available online only on the EphMRA website.

## 2.6 The Enquiry was:

13.21 says that written consent must be obtained at the start of the interview before recording starts for audio (or video) recording

How does this work for audio recording of telephone interviews? How can I get written consent?

## EphMRA's Response is:

EphMRA would advise that verbal agreement should be recorded and followed up with email, post or fax confirmation from the respondent.

## 2.7 The Enquiry was:

We are recruiting KOLs for a panel. We will conduct about 6 studies during this period for the client. The client does not want their identity revealed until all the studies have been completed.

Do we have to reveal the name of the client at recruitment stage?  
Can we reveal the name of the client at the end of all the studies if we make this clear at recruitment stage?

On a general note, can we recruit respondents to a project without revealing the name of the client if we make it clear at recruitment that the client's identity will not be revealed?

## EphMRA's Response is:

11.5 If the respondent asks (during recruitment or interview) where their name was obtained, they must be told. The respondents' right to this information overrides the client's right to confidentiality. If there is concern that this information will bias responses it is reasonable to provide this information at the end of the interview, assuming the respondent agrees to this.

Consequently if the client company supplied the potential respondent's name, they must be told the name of the study sponsor. If the sponsor did not supply the respondent's name there is no obligation to reveal the identity of the sponsor – at recruitment or during fieldwork.

Although there is an exception in Germany:

11.11 Germany federal data protection legislation requires that respondents are told the client company's identity if the client company supplied their name. This can be given at the end of the interview rather than the beginning, but it must be given.

If potential respondents' names are not supplied by the client company and it is important to the study findings to preserve the client's anonymity, it is reasonable at recruitment to inform potential respondents that they cannot be informed of the sponsor's identity (either at all or until all fieldwork is complete) and to screen out those for whom this is unsatisfactory. Clearly it would be sensible and courteous to explain why the sponsor's identity is being withheld.

### 3. ONLINE RESEARCH

#### 3.1 The Enquiry was:

I have a quick question regarding what respondents need to be told at recruitment for online focus groups/IDIs.

Obviously these are sort of face to face so I wondering whether the EFPIA obligations come into force and there needs to be a letter etc. confirming the details

I know that yesterday there was agreement that for online surveys the letter does not need to be signed and returned prior to fieldwork, but is this the case if recruitment has been done specifically for the study?

#### EphMRA's Response is:

Online market research – whether qualitative or quantitative, is excluded from EFPIA's ruling on recruitment agreements.

*Single stage market research studies conducted online, by telephone or by post do not require a written agreement in advance of fieldwork.*

EphMRA Code of Conduct 6.3 11.17, page 14

However in the UK, the BHBIA's Ethical & Legal Framework does require a documented agreement but: depending upon the study methodology or the means of recruitment, different mechanisms may be needed to capture agreement. For online studies, acceptance of agreement can be collected by asking respondents to 'click' on an acceptance box, a signature is not required.

### 4. Videostreaming

#### 4.1 The Enquiry was:

I have a question regarding archives of videostreamed interviews - up front at the recruitment stage we will obviously tell the respondents all the information that is necessary for them to give full consent.

One of these is which departments of the client will be watching the interviews either at the central location or via videostreaming.

If someone from a different department then watches the archive are we held responsible? We would have given the respondent all the information that we have to hand and I am not sure what we can do to stop the client from showing it to other people (other than relying on them abiding by the CoC!)

Is there a form that we should get the client to sign to agree that only the permitted people will be allowed to watch the archive

### EphMRA's Response is:

EphMRA would advise that all suppliers use a 'Respondent Permission Allowing Client Access to Recordings of Market Research Fieldwork' form – a pro forma for which is available in the appendices of the Code of Conduct (page 49 in the Code of Conduct 6.3 available online). This form requires the client to identify the functions/roles of those who will be viewing or listening to fieldwork recordings and to sign an agreement to this effect. By using this form and securing agreement from the client that only the agreed viewers/listeners will have access, the supplier has done as much as is reasonably possible to ensure that access to fieldwork recordings is not abused.

### 4.2 The Enquiry was:

We have recently had an enquiry about how to preserve confidentiality of respondents when using videostreaming. We have 2 questions:

- 1) We understand that in Germany the confidentiality laws / procedures are much stricter and that in effect by videoing a respondent you are automatically breaking confidentiality as the respondent is identifiable. Is this the case? If so how do we get around this?
- 2) When conducting all interviews at CL respondents are asked to sign consent forms for audio and video recording and told it will not be used for anything other than MR purposes. However, videostreaming companies seem to automatically archive all interviews. Do we need to get physicians permission to have interviews archived and possibly viewed by a wider audience? DO we at least need to inform them of the fact? How can we ensure we are maintaining confidentiality?

### EphMRA's Response is:

#### **1) German Confidentiality Laws / Procedures**

Recorded data (audio or video) given to clients without respondent permission must be anonymised. It is recognised that audio/video tapes may be difficult to anonymise as an individual's voice/appearance/turn of phrase/opinion may be identifiable, particularly in specialised healthcare fields where the respondent universe is small. In Germany if the recording identifies the respondent it cannot be given to the client even if permission was granted, federal data protection legislation forbids this.

*The Arbeitskreis Deutscher Markt- und Sozialforschungsinstitute e.V. (ADM) and the Berufsverband Deutscher Markt- und Sozialforscher e.V. (BVM) have therefore included a passage in the "Declaration for the Territory of the Federal Republic of Germany Concerning the ICC/ESOMAR International Code*

December 2010

*of Practice” in the overall interest of German, but also European, market and social research, prohibiting consent from being obtained to pass on data to third parties in a personalised form – based on the already existing principle of anonymisation and on the legal situation described – and thus also declaring this to violate professional ethics.*

Key Problems in the Data Protection Laws and Professional Laws for Scientific Survey  
Research  
[http://www.adm-ev.de/fileadmin/user\\_upload/PDFS/Kernprobleme\\_E.pdf](http://www.adm-ev.de/fileadmin/user_upload/PDFS/Kernprobleme_E.pdf)

Measures such as pixilation of faces, dubbing of voices, use of sub-titles can be used to disguise respondents on video tape, however it may be difficult to apply these measures other than retrospectively.

## **2) Respondent Consent for Archiving of Footage of Interviews**

The researcher/agency should store research records for an appropriate length of time - there are no absolute guidelines on how long this should be. This period will vary according to the nature of the data, the type of project and the need for future research or follow up analysis. Personal data (such as recruitment questionnaires) can be destroyed before non-personal data (such as tabulations). Data Protection legislation requires that personal data must be destroyed as soon as the purpose of the study is redundant.

Personal data should only be stored for future use if permission for this has been given, so individual respondent permission for archiving of video footage is required. Additional explicit consent would also be required if footage was to be viewed by a wider audience.

If video streaming has been used to allow remote viewing of fieldwork it is possible that the video transmission system used delivered a copy of the recording to the receiving computer. If this was the case the researcher must take steps to ensure that any copy of the video stream saved on the observer’s computer is deleted.

Respondents must also be made aware that they can ask at any time to know what personally-identified data about them are currently being held and for these to be amended or destroyed.

Researchers are responsible for the safe handling, processing, storage and disposal of market research and personal contact data.

For further detail see Section 14 of EphMRA’s Code of Conduct.

## 5. PRODUCT TESTING

### 5.1 The Enquiry was:

We have been approached by a pharmaceutical company to conduct a study with patients which should ideally include the intake of an approved substance (RX medication, ACTIVE INGREDIENT) LIVE in the central location. If a nurse is present, is this allowed as part of a market research study?

Would it be acceptable if -of course only with their consent- they tried a different and also available application form (syrup as compared to tablet) with the very same dosage at this occasion?

### EphMRA's Response is:

EphMRA guidelines upon the testing of products are as follows (see Section 13, page 17 of the Code of Conduct):

#### Testing Products and Devices

- 13.3 It is strongly recommended that placebos are used for product testing whenever practical.
- 13.4 Licensed prescription-only medicines can only be taken by a patient if a registered medical practitioner is present. If the product is unlicensed respondents cannot be asked to ingest it without the approval of a Research Ethics Committee.
  - The company must provide full product details including all ingredients.
  - Respondents must read and understand the details and must then sign a disclaimer.
- 13.5 If a respondent uses or handles active substance, medication or a medical application which might cause an allergenic or other undesirable effect, usage must be carried out according to Good Clinical Practice (GCP) guidelines. <http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf>
- 13.6 Clients are fully responsible for all damage or injury caused by materials or products they have provided to researchers for research purposes unless the researcher failed to take normal care of the materials/products when in their possession.
- 13.7 When the client entrusts products to an agency researcher's care, the client commits themselves to providing products compliant with laws in force and to give all the necessary information on these products, providing in particular correct information on the directions for use, the ingredients/components list and the transport and storage conditions. Moreover, the client must take

the necessary measures to provide the researcher with any constraints relating to the security of the products.

[www.esomar.org/uploads/professional\\_standards/guidelines/mutual\\_rights/Guideline\\_on\\_mutual\\_rights\\_and\\_responsibilities\\_V4\\_consultation\\_final.doc](http://www.esomar.org/uploads/professional_standards/guidelines/mutual_rights/Guideline_on_mutual_rights_and_responsibilities_V4_consultation_final.doc) Aug 2009

- 13.8 As with stimulus material, products and devices (active or placebo) must be collected at the end of the interview.
- 13.9 Companies should refer to their medical and regulatory departments for additional guidance.

As the study in question may involve taking two preparations EphMRA recommends great caution with regard to dosing, to ensure that patients do not ingest more than the recommended dose at any one time.

**EphMRA strongly recommends** that the commissioning company's drug safety department is consulted and their advice and involvement sought whilst planning and executing the study.

## 6. CERTIFICATION

### 6.1 The Enquiry was:

I have a client who has asked for signed documentation that we adhere to the Italian Data Protection Code. In the UK, we can provide certification that we abide by BHBA's code of conduct, which encompassed all UK data protection legislation.

As the EphMRA code of conduct ensures that local EU data protection laws are adhered to, is there a similar way we can show we adhere to EphMRA code of conduct / have you any advice on how best to respond to the request?

### EphMRA's Response is:

EphMRA does not provide any certification that member organisations agree to adhere to its Code of Conduct. Unlike the BHBA's Ethical and Legal Guidelines, EphMRA's Code of Conduct is discretionary, rather than mandatory. So whilst EphMRA strongly encourages and promotes adherence to its Code of Conduct it cannot provide confirmation that member organisations do so.

In responding to a request about compliance credentials, it is entirely reasonable that any member company emphasizes their membership of EphMRA and their adherence to the Code of Conduct which necessarily entails adhering to local regulations including the Italian Data Protection Code.

## 7. Use of Product Name in market research

### 7.1 The Enquiry was:

The question is about disguised promotion.

A company may conduct an online quantitative project across 6 markets (UK, Germany, Netherlands, Spain, Sweden, Norway, Denmark) and approximately 700-750 physicians.

The research is about a product in development which does not have marketing authorisation in any of the countries where we are undertaking the research. It is the only product available/in development with this particular active ingredient.

Is it okay to mention the generic name within the product profile where we introduce the type of product? The name would only be mentioned once but it is clearly the only product with that specific generic name.

### EphMRA's Response is:

There are no regulations that EphMRA is aware of that forbid the use of the product's generic name within market research studies however we would advise against it unless it is vital to achieving the study objectives, even then there are likely to be risks attached. The EphMRA Code of Conduct makes it clear that:

10.1 Market research must not be used as a means to influence the attitudes or behaviour of respondents. It must not be used for the direct purposes of promotion or selling, generally referred to as 'selling under the guise of' or 'disguised promotion'.

Widespread use - within for instance a large scale international market research study - of the generic name could be deemed promotional, particularly if it could not be justified in the light of the MR objectives, and the sponsoring company could be vulnerable to a complaint of disguised promotion.

13.10 The unnecessary or repeated use of brand names should be avoided unless assessing reaction to the name, or use of the product by name is an essential research objective.

EphMRA would advise the same caution with generic names – particularly if they are unique and the product is as yet unlicensed.

13.11 Within any market research care must be taken to ensure that respondents understand when they are providing feedback on draft materials, hypothetical scenarios, assumptions, a product in development or as yet unlicensed.

13.12 Where required (country requirement or company policy) stimulus materials to be used within market research should be approved by the client company's medical department prior to use (irrespective of format or finish).

December 2010

We would recommend that use of the product name is avoided if at all possible, if it is not, the advice and approval of the medical department should be sought.