



Adverse Event Reporting an Update For the Annual Conference Malta 2007

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on behalf of the EphMRA AE Working Group**

AE Working Group

- Allan Bowditch – Ziment – AE WG Co Chair
- Francois Feig – Merck Serono/EphMRA Past President/AE WG Co-chair
- Dan Fitzgerald - GfK US
- Rob Haynes - Schering Plough
- Kerstin Lilla - Solvay
- Pia Nicolini – Brintnall & Nicolini
- Wayne Phillips - Double Helix/EphMRA AM Spokesperson
- Erich Wiegand - ADM

What has been done so far ?

- **June 2006** : address AE reporting at EphMRA conference & workshops
- **July 2006** : creation of the AE Working Group
- **September 2006** : provisional draft set of Guidelines, review by members and other associations
 - Several IDI's with Drug Safety Directors
 - obtain a better perspective of what would constitute an optimal solution
- **November 2006** : evaluation by wider sample of Drug Safety personnel through EphMRA and PBIRG
- **January 2007** : guidelines distributed to EphMRA members
- **February 2007** : presentation and discussion at IMM
- **March 2007** : assesment of MR agencies obligations on AE to Pharmacos.
- **March/April 2007** : continuing dialogue with ABPI/BHBIA Working Group.



What are Current Standards for Reporting AEs?

The two main pillars of pharmacovigilance are:

- Voluntary reporting (from health professionals and consumers in some places)
- Mandatory reporting from manufacturers and distributors of pharmaceutical products

Evolution of Responsibility in AE Reporting

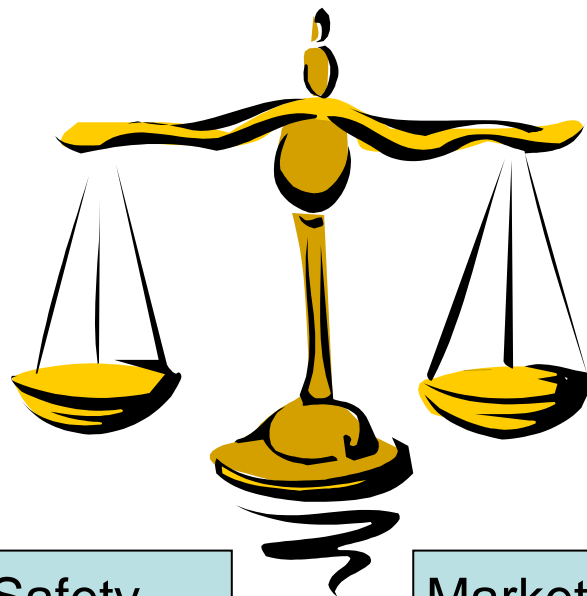
- Increasing concerns from pharmaceutical manufacturers and from regulatory agencies
- Expanded definition of comprehensiveness in reporting by pharmacovigilance departments
- Responsibilities of pharmacos extend to all employees and to all persons acting as “agents” of the pharmacos, -- however there are various interpretations of who this does encompass and in what context.

What, if Anything, Should be Reported?

- Any **serious** AE must be reported, irrespective of labeling
- If in the course of a marketing research exercise information emerges relating to AE then the following action should be taken **if the following 4 criteria are met.**
 - The ADR/AE is identified as being, or thought to be, linked to a specific drug
 - The ADR/AE is a clearly identifiable reaction
 - The ADR/AE is provided by an identifiable reporter (physician/ patient)
 - The ADR/AE is linked to an “identifiable patient” – not necessarily named



EphMRA's Position



Patient Safety

Market Research Integrity

What are the concerns?

- A question of privacy and confidentiality
- A question of disrupting the natural flow of research/adding burden to the research
- A question of threatening the relationship of market researcher and respondent
- A question of “know-how”
- A question of liability and indemnity
- A question of increased costs to clients
- A question of potential future bias if “pool” of respondents is diminished.

EphMRA Advocates the Following Approach for Handling a Reportable AE

The physician (or patient) to be informed that such information is required by the Pharma company as part of pharmacovigilance,

- They should be informed either at the time of the information being stated or at the end of the interview, that they should report the details to the drug company (physician), or in the case of the patient, to their physician.



HOWEVER!!!

- This approach is not sufficient to satisfy the position agreed by the ABPI/BHBIA and endorsed by MHRA in the UK.
- It is also not a position that some Pharmacos will accept.
- BUT it is an approach that is agreed by many Pharmacos (at this time) and is an acceptable approach for many countries.



Timing

- AE meeting the 4 criteria should be submitted ASAP, preferably within 24 hours
- In cases where the AE could not be identified immediately, the time starts when the AE has come to light
- Reports should be sent to the commissioning client regardless of the country where the AE occurred

The EphMRA Guidleines

- The Guidelines are intended as a simple "framework" for EphMRA members.
- They are not set out to match the exact wording of Pharmcovigilance documention.
- They cannot be considered legally binding
- However, it is hoped that most companies will agree with the principles behind the guidelines prepared.



Syndicated and Audit Data (1)

- If MR agency conducts a syndicated investigation (own initiative)
 - No legal obligation to provide details of AE's to MA
 - No AE reporting required
- If special questions are asked by clients leading to AE mentioning
 - Same guidance as for custom MR projects

Syndicated and Audit Data (2)

- If MR agency conducts a syndicated project (initiative of several Pharmacos)
 - Same guidance as for custom MR projects
- However, if a syndicated project is developed by a MR agency and marketed to the industry, in general no reporting requirement exists.

Syndicated and Audit Data (3)

- **IN SUMMARY**
- Audits (especially diary) purchased by any Pharmaco
 - No legal obligation for pharmacos to provide details of AE's **when looking at aggregate data**
 - Where **individual patient records**, containing all the relevant fields for a reportable AE, are purchased from a syndicated patient level diary study, **then these need to be reported by the Pharmaco**

Training

- EphMRA is examining the training issue.
- We are considering how and if such a program might be implemented by EphMRA or by other organizations. This would have several advantages:
 - It will be an approved standardized training program.
 - It is hoped that most if not all pharmacos will “buy into” the process, only one procedure will need to be followed.

Commonly Asked Questions

- What is and AE/ ADR
- When does a Physician need to be reminded to report an AE/ADR, or if agreed with the client when does the MR agency need to report such an event.
- Why does MR have to become involved in AE reporting?
- What should I do if senior staff in a Pharma Company ask that only physicians who consent to allow their names to be passed on to the company if an AE linked to a patient for the company's product is mentioned, be allowed to participate in the research?
- In Germany, the BVA has indicated that Physician confidentiality is sacrosanct and studies that require the physician's name to be passed onto a Pharma Company in the event of an AE having to be reported should not be undertaken by a German MR agency or fieldwork organization. What can be done in this situation?

Commonly Asked Questions Cont.

- What AE information has to be reported?
- Is there a difference in the time that should be allowed to report an AE depending on how long the product has been available on the market?
- Is there a difference between what might be regarded as a “serious” AE and one that is not “serious”?
- In relation to the question above, what happens if the study is on –line and the AE information is not discovered until the coding stage as no one will have seen the data until then?
- If I am conducting a MR project for client “A” and an AE that is technically reportable occurs in an interview for a competitive drug, does that have to be reported to Company “B”?

Commonly Asked Questions Cont.

- If an MR agency is involved in conducting syndicated investigations and an AE that is reportable occurs, what does the MR agency do?
- Different Pharma clients have slightly different training programs that MR agencies need to agree to examine and follow if they are to be approved for conducting MR for that company, can we not have a standard set of training procedures that all companies can agree we should follow?
- Should we try to prepare questionnaires in such a way to try to reduce any likelihood of an AE occurring during the course of an interview?
- Do we have to ask Drug Safety personnel to approve our MR questionnaires?
- What if any precautions are needed if MR investigations to examine patients on a longitudinal basis are carried out?



THANK YOU