1st EudraVigilance Information Day, 8 May, 2006

Electronic Transmission of Individual Case Safety Reports in the European Economic Area and EudraVigilance: the Current Achievements

EMEA, Canary Wharf, 7 Westferry Circus, London E14 4HB, UK

Programme Committee

- Dr. Gaby Danan (EV-EWG chair), sanofi-aventis, France & EFPIA Representative
- Sabine Brosch (EV-EWG chair), EMEA, EU
- Elmar Kroth (AESGP), German Medicines Manufactures Association, Germany
- Anja van Haren, Medicines Evaluation Board, The Netherlands

Need for this EudraVigilance Information Day

The exchange of adverse reaction data in the frame of pharmacovigilance in the pre- and post-authorisation phase is now a regulatory requirement. For marketing authorisation holders and sponsors of clinical trials it is, therefore, of major importance to understand and meet these requirements to be able to operate on the basis of a common standard that avoids duplication of efforts. Indeed, as more stakeholders gain practical experience, it is important to share learnings so that broader implementation may leverage these data standards in the interest of improving data consistency and interoperability in the frame of the EU pharmacovigilance. This meeting will provide participants with the opportunity to recognize the regulatory aspects of adverse reaction reporting in line with the revised Volume 9 A as well as to learn from the practical experience gained by regulators, marketing authorisation holders and sponsors.

EudraVigilance Information Day Goals

Desired Outcomes:

- Organize the electronic reporting of ICSRs within your company/organisation
- Share knowledge about the current implementation status and the next developments in the Community
- Recognize the importance of the activities of the EudraVigilance Steering Committee and Expert Working Group in supporting the implementation activities of electronic reporting of adverse reactions in the EU

At the conclusion of this EV Info Day, participants should be able to:

- Explain the current regulatory requirements and the status of electronic reporting of ICSRs (clinical trials and post-authorisation) in the EU
- Identify the lessons learned regarding the implementation of the electronic reporting of ICSRs from the regulator and industry/sponsor perspectives
- Describe the EudraVigilance system and its use in supporting pharmacovigilance and risk management activities

EudraVigilance Information Day Audience

This programme will benefit individuals involved in:

- Qualified Persons and pharmacovigilance staff
- Clinical Data Management
- Clinical Research and Development
- Dictionaries/Data Standards
- Information Management

Date & Location:
8 May, 2006
EMEA
London, UK

Overview

As of 20 November 2005, electronic reporting is mandatory across the European Economic Area (EEA). This is in accordance with Regulation (EU) No. 726/2004 and Directive 2001/83/EC as amended. Furthermore, for Suspected Unexpected Serious Adverse Reactions (SUSARs) occurring during clinical trials, electronic reporting requirements are defined in the implementing texts of Directive 2001/20/EC. The exchange of Individual Case Safety Reports (ICSRs) based on the standards agreed at the level of the International Conference on Harmonization (ICH) has been widely implemented and paperless submissions to the EMEA and many EU national Competent Authorities is now a reality.

The electronic transmission of ICSRs is a key element in improving the process of adverse reaction reporting in pharmacovigilance. It is not only a major step forward in providing information more rapidly but also in standardizing the way clinical safety data elements are presented, thereby improving the collective ability to evaluate complex data.
The programme will address the latest status in the EEA regarding the electronic reporting initiatives from Regulator, Industry and non-commercial sponsor perspectives. The particular areas which will be covered in depth are:

An overview of the current implementation achievements:

- The industry/sponsor perspective on the practical implementation aspects and operational concerns regarding the integration and use of the interdependent ICH E2B(M), M2 and M1 (MedDRA) guidelines and standards at Community level
- The coordination of the implementation activities at Community level on the basis of the newly established EudraVigilance Expert Working Group (EV-EWG) and the EudraVigilance Steering Committee
- The current achievements and the further developments of the EudraVigilance System in view of supporting the pharmacovigilance activities and risk management initiatives from the perspective of the EMEA
- The lessons learned based on practical examples
- Part III of the revised Volume 9A and the 'Guidelines for Marketing Authorisation Holders, Competent Authorities and the Agency on the Electronic Exchange of Pharmacovigilance Information in the EU'

Panel discussions will provide the opportunity for extensive Q&As with the experts.

Details of the EudraVigilance Information Day

Duration:	1 day
Location:	EMEA, Canary Wharf, 7 Westferry Circus, London E14 4HB, UK
Capacity:	This course is limited to 140 participants, divided in to two rooms

EudraVigilance Information Day Agenda

Introduction & Session 1

08:45 **Introduction**
Welcome and introduction by Professor Kent Woods, MHRA, UK

09:15 **Session 1**
Session Chair: Professor Kent Woods, MHRA, UK
Member State perspectives on e-reporting of ICSRs

The electronic reporting initiatives from the perspective of Member States such as the Medicines Evaluation Board (NL) and the Paul-Ehrlich Institute (PEI-DE) in line with the mandatory electronic reporting requirements as defined in Regulation (EU) 726/2004 and Directive 2001/83/EC, as amended will be presented. Electronic reporting of suspected unexpected adverse reactions (SUSARs) in the frame of Directive 2001/20/EC will be also discussed. Regulatory aspects, current achievements and further developments will be addressed.

Anja van Haren, Medicines Evaluation Board, The Netherlands
"Electronic reporting: approaches and achievements in the Netherlands"

Dirk Mentzer, Paul-Ehrlich Institute, Germany
"Electronic reporting: approaches and achievements by the Paul-Ehrlich Institute in Germany"

Speaker from Member State invited (to be confirmed)

Panel Discussion

10:45 Coffee break

Session 2

11:00 **Session 2**
Session Chairs: Professor Kent Woods, MHRA, UK and Gaby Danan, sanofi-aventis, France & EFPIA Representative
Current achievements and lessons learned from an industry /sponsor perspective

In the light of the current regulatory requirements in the pre- and post-authorisation phase, the critical success factors for the electronic transmission of ICSRs using the ICH E2B(M), M2 and MedDRA guidelines and standards in the EU as well as feedback on the practical experience are presented from an industry and sponsor point of view.

Hans-Peter Kraemer, Bayer Healthcare, Germany & EFPIA Representative
"Legal framework of electronic ADR reporting and the challenges in the daily practice from the globally acting industry perspective"
- Local differences in the implementation
- Handling of Community language and other challenges

Elmar Kroth, AESGP, Germany
"Joint approaches for small and mid-sized companies to comply with new pharmacovigilance requirements"
- Specific situation of small and mid-sized companies
- Potential for joint approaches, e.g. for electronic submission of ICSRs

Wendy Huisman, EGA, The Netherlands
"Pragmatic approaches, challenges and proposals from a generic perspective"
- Product dictionary - pragmatic approaches
- Literature duplicates - challenges
- Authority reports - practical solutions

Nathalie Dubois, EORTC, Belgium "Electronic SUSAR reporting following the implementation of the Clinical Trial Directive 2001/20/EC, experience of a non-commercial sponsor of clinical trials"

Panel Discussion including **Jean-Paul Dutertre, EuropaBio, Europe**

12:30 Lunch (available in-house, not included)

Session 3

13:30 **Session 3**
Session Chairs: Professor Kent Woods, MHRA, UK and Sabine Brosch, EMEA, EU
EudraVigilance: current achievements and ways forward

The current implementation status of the electronic reporting in relation to EudraVigilance as well as the next developments in the area of data analysis and signal detection will be presented.

Tom Paternoster, EMEA, EU
Adverse reaction reporting requirements in line with Volume 9A and current achievements in the pre- and post-authorisation phase.

Nick Halsey, EMEA, EU
Electronic reporting: what to do in case of system failure?

Stefano Cappe, EMEA, EU
Signal Detection and Data Analysis Tools in EudraVigilance

Panel Discussion

15:00 Coffee break

Session 4

15:15 **Session 4**
Session Chairs: Sabine Brosch, EMEA, EU and Gaby Danan, sanofi-aventis, France & EFPIA Representative
The activities of the EudraVigilance Expert Working Group

The activities of the EudraVigilance Expert Working Group and the practical aspects related to the requirements of Part III of the revised Volume 9A and the 'Guidelines for Marketing Authorisation Holders, Competent Authorities and the Agency on the Electronic Exchange of Pharmacovigilance Information in the EU' and the implementing texts of Directive 2001/20/EC will be discussed.

Sabine Luik, Boehringer Ingelheim, Germany
"e-reporting requirements and points to consider in the pre-authorisation phase in line with the implementing texts of Directive 2001/20/EC"

Nick Phillips, Roche, UK
"e-reporting requirements and points to consider in the post-authorisation phase in line with Volume 9A"

François Maignen, EMEA, UK
Signal detection and data analysis methods at Community level"

Panel discussion

Session 5

16:45 **Session 5**
Session Chairs: sanofi-aventis, France & EFPIA Representative and Sabine Brosch, EMEA, EU
Question and Answer Session with all speakers.

17:15 End of day

Registration Form

Fax to: +41 61 225 51 52

EudraVigilance Information Day ID 06540 - 8 May, 2006
EMEA, London, UK

Registration will be accepted by mail, fax or email - Registration includes material and coffee-breaks; lunches not included
This EudraVigilance Information Day will be limited to 140 participants.

Standard Fee	**EUR 300.00** ❑
Non-Commercial Fee	**EUR 150.00** ❑

Note: Payment of registration fees must be received before commencement of the course

Hotel and Travel Information

Recommended hotels nearby the EMEA
Attendees must make their own hotel reservation
Ask for available EMEA rate at:

Hilton London Docklands Riverside
265 Rotherhithe Street, London , SE16 5HW, UK
Telephone: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: sales_docklands@hilton.com

The International Hotel, Docklands
Marsh Wall, London E14 9SJ, UK
Tel : +44 207 712 0100
Fax : +44 207 712 0102
E-mail : res712@britanniahotels.com

Registrant

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name		Company	
First Name & Middle Initial		Job Title	
Street Address / P.O. Box		Postal Code	
City		Country	
(*)Telephone		(*)Telefax	
E-Mail			

(*) A telephone and fax number are required for faxed confirmation

Payment

Please check payment method

❑ **Cheques should be made payable to**: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, Elisabethenanlage 11, Postfach, 4002 Basel, Switzerland.

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be in EURO and your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your DIA account. **Your name and company must be included on the transfer document to ensure payment to your account.**

❑ **Please charge my credit card** - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ **VISA** ❑ **MC** ❑ **AMEX** Exp Date _____ Card # _____

Signature _____

Cancellation Policy

PRIOR TO 5 DAYS BEFORE THE EUDRAVIGILANCE INFORMATION DAY - MAY 1, 2006

An administrative fee will be deducted from the registration fee: EUR 100.00

Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. Cancellations must be in writing. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

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