5th EudraVigilance Information Day

6 October, 2008 at the EMEA, London, UK

EudraVigilance

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

Programme Committee

- Prof. Kent Woods (Co-Chair EudraVigilance Steering Committee, EV-SC), Chief Executive, MHRA, UK
- Dr. Gunilla Sjölin-Forsberg, Läkemedelsverket (MPA), Sweden (Member of the EudraVigilance Steering Committee)
- Dr. Sabine Brosch (EudraVigilance Expert Working Group, EV-EWG Co-chair), Deputy Head of Sector, Pharmacovigilance, EMEA, EU
- Dr. Gaby Danan (EudraVigilance Expert Working Group, EV-EWG Co-chair), Expert Global Pharmacovigilance and Epidemiology, sanofi-aventis, France & EFPIA Representative

DIA Drug Information Association

Need for this EudraVigilance Information Day

The establishment of a fully operational and completely populated EudraVigilance System to support the EU pharmacovigilance and risk management activities is still one of the priorities of the EMEA's work programme in 2008. Furthermore, the electronic exchange of adverse reaction data in the pre- and post-authorisation phase is a regulatory requirement in line with Volume 9A and Volume 10 of Eudralex (http://pharmacos.eudra.org).

The EudraVigilance Information Day will provide a forum for marketing authorisation holders and sponsors of clinical trials to gain a better understanding of the eight key activities of the EudraVigilance Expert Working Group in line with their work programme 2008 (see http://eudravigilance.emea.europa.eu).

The main areas that will be addressed are as follows:

- Examples of implementation of electronic reporting of ICSRs in some of the EU Member States and Canada
- Practical implementation questions raised by stakeholders with main focus on electronic reporting of ICSRs and EudraVigilance including SUSARs in clinical trials
- Update on ICH activities in collaboration with Standard Development Organisations (SDOs) with main focus on:
  - The revision of the ICH E2B(R2) guideline
  - The ICH M5 topic on Data Elements and Standards for Drug Dictionaries
- Pharmacovigilance inspections in Europe and Canada

Panel discussions will provide the opportunity for extensive Q&As with the speakers and Programme Committee members.

EudraVigilance Information Day Goals

Desired Outcomes

- Operate the electronic reporting of ICSRs within your company/organisation in line with the regulatory requirements across the Community
- Share knowledge about the current implementation status of electronic reporting and the next developments in the EU and ongoing activities at ICH level
- Understand pharmacovigilance inspections and share knowledge about how to be compliant with the current requirements

At the conclusion of this EudraVigilance Information Day, participants should be able to:

- Explain the specific aspects to be taken into account in relation to the reporting requirements in line with Volume 9A part III and Volume 10 of Eudralex
- Describe the developments in relation to ICH and the importance for the planning of the future upgrades of pharmacovigilance databases
- Describe the main findings of Pharmacovigilance inspections

EudraVigilance Information Day Audience

This programme will benefit Qualified Persons responsible for Pharmacovigilance and individuals involved in:

- Pharmacovigilance
- Clinical Data Management
- Clinical Development
- Information Management
- Safety databases

Details of the EudraVigilance Information Day

Duration:	1 day, Monday, October 6, 2008, 08.45 - 17.00
Location:	EMEA, Canary Wharf, 7 Westferry Circus, London E14 4HB, UK
Capacity:	This course is limited to 120 participants

Date & Location:
6 October, 2008
EMEA
London, UK

EudraVigilance Information Day Agenda

Introduction & Session 1

08:45 **Welcome**
Head of PhV-PASE Sector, EMEA, EU

09:00 **Session 1**
Session Chair: Professor Kent Woods, MHRA, UK
Pharmacovigilance Systems: Canada and Spain

As part of this session, the pharmacovigilance systems of Health Canada and Spain will be presented focusing on the Agencies' pharmacovigilance databases and their approach towards signal detection and risk management. Furthermore, the implementation activities regarding the electronic reporting of Individual Case Safety Reports (ICSRs) will also be addressed.

The Pharmacovigilance System of Health Canada
Heather Sutcliffe, Director, Marketed Health Products Safety and Effectiveness Information Bureau, Health Canada, Canada

FEDRA: Spanish Pharmacovigilance Database
Edurne Lazaro, Agemed, Agencia Española de Medicamentos y Productos Sanitarios

The Pharmacovigilance System of a National Competent Authority in the EEA
Speaker invited

Panel Discussion

10:40 Coffee break

Session 2

11:00 **Session 2**
Session Co-chairs: Dr. Gunilla Sjölin-Forsberg, MPA, Sweden and Dr. Gaby Danan, Sanofi-Aventis, France
Volume 9A and Volume 10: Implementation Questions related to Adverse Reaction Reporting

This session will provide the participants with the possibility to learn about and discusses key implementation questions related to adverse event/reaction reporting in the pre- and post-authorisation phase. Highlights in relation to Volume 9A and Volume 10 will be summarised. Furthermore, participants will be invited to submit questions to the panel in advance of the meeting.

Volume 9A: Implementation Questions and Answers
Subhash Mistry, GlaxoSmithKline, Global Clinical Safety and Pharmacovigilance, UK
EMEA Speaker invited

Volume 10: Implementation Questions and Answers
Dr. Brian Davis, MHRA, Medicines and Healthcare Products Regulatory Agency, UK

Panel Discussion

12:30 Lunch

Session 3

13:40 **Session 3**
Session Co-chairs: Professor Kent Woods, MHRA, UK and Dr. Gaby Danan, Sanofi-Aventis, France
Development of ICH E2B(R3) and M5 Technical Standards: Current Status and Next Steps

In October 2006, the International Conference on Harmonization (ICH) Steering Committee and its expert working groups agreed on the collaboration with accredited Standard Development Organisations (SDOs) to leverage the development of technical standards for ICH e-Initiatives. Expanding ICH standards globally would fulfil ICH's vision of the future development of more efficient processes and increased uniformity of drug development requirements globally without compromising the quality, safety, and efficacy standards expected by practitioners and patients.
The purpose of this session is to provide participants with the opportunity to gain insight on how the collaboration between ICH and the SDOs is organised and how the technical standards are being developed, tested and agreed upon. Key areas of changes as regards ICH E2B and the link with ICH M5 will be addressed as well as the potential timelines for release of the new standards and the implementation at ICH level.

Development of ICH E2B(R3) and M5 Technical Standards in collaboration with SDOs
Andrew Marr, Director, e-Regulatory Development Global Regulatory Operations, GSK, UK

The new ICH E2B(R3) Individual Case Safety Report: current status and next steps
EMEA Speaker invited

ICH M5 'Data Elements and Standards for Drug Dictionaries': current status and next steps
Sabine Brosch, Pharmacovigilance and Post-Authorisation, Safety and Efficacy of Medicines, EMEA, EU

Panel Discussion
Anja van Haren, national expert of Medicinies Evaluation Board (MEB) at EMEA

15:10 Coffee break

Session 4

15:30 **Session 4**
Session Co-chairs: Dr. Gunilla Sjölin-Forsberg, MPA
Professor Kent Woods, MHRA, UK
Pharmacovigilance Inspections: Main findings and Points to Consider

The objective of this session is to provide participants with an overview of main findings during pharmacovigilance inspections and points that should be taken into account. Furthermore, the overall approach of Health Canada in conducting pharmacovigilance inspections will be also presented.

Good Pharmacovigilance Practice: common inspection findings and current areas of concern
Anya Sookoo, MHRA Expert Inspector, GCP & Pharmacovigilance, Medicines and Healthcare Products Regulatory Agency, MHRA, UK

Pharmacovigilance Inspections: points to be taken into account
Vicki R Edwards, QPPV/Senior Director, European Pharmacovigilance Global Medical Services, Abbott, UK

Pharmacovigilance Inspections at Health Canada
Heather Sutcliffe, Director, Marketed Health Products Safety and Effectiveness Information Bureau, Health Canada, Canada

Panel Discussion

17:00 End of day

Registration Form

Fax to: +41 61 225 51 52

EudraVigilance Information Day ID# 08537 - 6 October, 2008

EMEA, London, UK

Registration will be accepted by mail, fax or email - Registration includes material, coffee breaks and sandwich lunch.

This EudraVigilance Information Day will be limited to 120 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 near 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		(*)Fax	
Email			

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

Payment

Please check payment method

❑ **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 _____

❑ **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 25, 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 ID# 08537 and invoice number, must be included on the transfer document to ensure correct allocation of your payment. **Payments must be net of all charges.**

Cancellation and Transfer Policy

Cancellations must be made in writing and be received at the DIA Europe office by 17:00 CET on September 29, 2008.
Cancellations received by this date are subject to an administrative fee of 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 and travel reservations. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or any other costs incurred by registrants. DIA Europe reserves the right to alter the venue and dates if necessary.

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible. You may transfer your registration and payment, once only, from one course to a future date of that same course. If you are unable to attend the new date selected, there will be no refund of the registration fee.

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