EudraVigilance Information Day

Course #11520
10 May 2011
European Medicines Agency, London, UK

Programme Committee

Prof. Kent Woods
Chief Executive, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
Co-Chair EudraVigilance Steering Committee (EV-SC)

Peter Arlett
Head of Pharmacovigilance and Risk Management Sector
European Medicines Agency, EU

Sabine Brosch
Business Lead EudraVigilance and International Standardisation in Pharmacovigilance
Business Co-ordination and Scientific Projects
Pharmacovigilance and Risk Management Sector
European Medicines Agency, EU

Gaby Danan
Pharmacovigilance Expert, France
Former EU Qualified Person for Pharmacovigilance
sanofi-aventis

Who Will Attend

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

- Pharmacovigilance
- Clinical Development
- Information Management
- Safety databases

Details of the EudraVigilance Information Day

Location: European Medicines Agency
Canary Wharf
7 Westferry Circus
London E14 4HB, UK

Capacity: The event is limited to 120 participants

The New Pharmacovigilance Legislation – Focus on EudraVigilance, Adverse Drug Reaction Reporting and Benefit-Risk Management Planning in the EU

Need of this EudraVigilance Information Day

Following adoption by the Council and the European Parliament, the new legislation on pharmacovigilance was published on 31 December 2010 in the Official Journal of the EU. The new legislation, a Regulation and a Directive, will become applicable in July 2012.

This legislation is the outcome of the legal proposals on pharmacovigilance that the Commission put forward in December 2008. The new legislation will strengthen and rationalise the current system for monitoring the safety of medicines on the European market. It will improve patient safety and public health through better prevention, detection and assessment of adverse reactions to medicines. For example, it will allow patients to report adverse drug reactions directly to the competent authorities and reporting of adverse reactions will be broadened to cover, medication errors. Furthermore, the format and content of PSURs will be revised and the review streamlined resulting in a single assessment of periodic safety update reports for different medicinal products containing the same active substance or the same combination of active substances.

The EudraVigilance Information Day will provide a forum for medicines regulatory authorities, marketing authorisation holders and sponsors of clinical trials to gain updates on the new legislation in pharmacovigilance, the key activities of the EudraVigilance Expert Working Group in line with their work programme for 2011 (see http://eudravigilance.emea.europa.eu) and the recent developments as regards the international standardization activities in pharmacovigilance.

The programme will address the following areas:

- An overview of the new features and key changes introduced by the new pharmacovigilance legislation
- The new pharmacovigilance legislation and the impact on EudraVigilance and stakeholders
- Transition from the current to the new reporting rules
- Benefit risk management planning
- Periodic Safety Update Reporting and the revision of the ICH E2C guideline
- Considerations for Quality Systems and the Pharmacovigilance System Master File
- Practical implementation questions from stakeholders on adverse reaction reporting under the current legal framework

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

EudraVigilance Information Day Goals

Desired outcome:

- Share knowledge about the new pharmacovigilance legislation and its impact on the conduct of pharmacovigilance in the EU
- Operate the electronic reporting of ICSRs within a company/organisation in line with the regulatory requirements across the Community
- Share knowledge on the initiatives of the European Medicines Agency to improve the quality of pharmacovigilance data held in EudraVigilance and the anticipated impact on stakeholders

EudraVigilance

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA®
www.diahome.org

TUESDAY | 10 MAY 2011

08:30 **REGISTRATION**

09:00 **Key Note**

THE NEW PHARMACOVIGILANCE LEGISLATION AND IMPLEMENTATION PLANNING

Peter Arlett, Head of Sector, Pharmacovigilance and Risk Management, EMA, EU

09:40 **Session 1**

THE NEW PHARMACOVIGILANCE LEGISLATION AND CHANGES TO THE ADR REPORTING

Session Chair: **Peter Arlett**, EMA, EU

This session will address the changes to the adverse reaction reporting rules and the application of the transitional reporting measures until the successful completion of an independent audit on EudraVigilance. This will include the new responsibilities for the Agency as regards the notification of suspected adverse reaction reports occurring in the Union to the World Health Organisation (WHO).

The New Pharmacovigilance Legislation and Changes to the ADR Reporting
Sarah Morgan, MHRA, UK

10:30 **COFFEE BREAK**

11:00 **Session 2**

THE NEW PHARMACOVIGILANCE LEGISLATION AND THE IMPACT ON EUDRAVIGILANCE

Session Co-Chairs: **Sabine Brosch and Anja van Haren**

With the new legislation the role of EudraVigilance will be further strengthened to support the pharmacovigilance activities in the EU. This session will outline the key changes to EudraVigilance including the planning for the implementation of the new international Individual Case Safety Report (ICSR) standard. The Agency's initiative to improve the quality of ICSRs in EudraVigilance will be also addressed taking into account the future role of marketing authorization holders and the Member States to ensure the quality and integrity of the reported information to EudraVigilance.

EudraVigilance in the Context of the New Legislation
Sabine Brosch, EMA, EU

EudraVigilance Data Quality Management
Tom Paternoster, EMA, EU

The New International Standard for Individual Case Safety Reports (ICSRs)
Nick Halsey, EMA, EU

12:30 **SANDWICH LUNCH**

13:30 **Session 3**

THE NEW PHARMACOVIGILANCE LEGISLATION: QUALITY SYSTEMS, PHARMACOVIGILANCE SYSTEM MASTER FILE, PERIODIC SAFETY UPDATE REPORTS AND BENEFIT-RISK MANAGEMENT

Session Chair: **Peter Arlett**, EMA, EU

This session will provide an overview of the new provisions in relation to the content and maintenance of the pharmacovigilance system master file, as well as the minimum requirements for the quality system for the performance of pharmacovigilance activities. The impact of the new provisions applicable to the submission of periodic safety update reports and the revision of the ICH E2C guideline will be also presented. In addition, the planning of the benefit-risk management activities by pharmaceutical companies in the context of the new legislation will be addressed.

Considerations for Quality Systems and Pharmacovigilance System Master Files
Fergus Sweeney, EMA, EU

Periodic Safety Update Reports and the Revision of the ICH E2C Guideline
Georgy Genov, EMA, EU

Benefit-Risk Management Planning
Thomas Goedecke, EMA, EU

15:00 **COFFEE BREAK**

15:30 **Session 4**

QUESTIONS AND ANSWERS ON ADR REPORTING UNDER THE CURRENT LEGAL FRAMEWORK

Session Chairs: **Anja van Haren and Gaby Danan**

This session will focus on the release of new Questions and Answers in the context of Volume 9A and Volume 10 of the Rules Governing Medicinal Products in the EU. Furthermore, the outcome of the user survey on the Important Medical Events (IME) List will be presented with an outline of the next steps

New Questions and Answers on Volume 9A and Volume 10
Gilles Touraille, EMA, EU and Subhash Mistry, GSK, UK

MedDRA Important Medical Events (IME) List – Current Status and Next Steps
Ana Hidalgo-Simon, EMA, EU

17.00 **END OF THE INFORMATION DAY 1**

HOTEL INFORMATION

Recommended Hotel:

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

DIA was able to negotiate a special rate for participants of the Information Day: Room rate is GBP 137.00 per room incl. breakfast excl. VAT

To book a room, click here. Please fill in corporate account number: 481223696. The hotel is situated opposite of Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance to the European Medicines Agency (2 min). The ferry ticket is included in the room rate. Please make sure you receive it when checking in.

For further information, please click on the link below:
http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

DIA Upcoming Training Courses in Safety and Pharmacovigilance

Benefit/Risk Management
19-20 May 2011 | Prague, Czech Republic | ID 11562

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
3-7 October 2011 | Zagreb, Croatia | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections
10-11 May 2011 | Amsterdam, The Netherlands | ID 11542
November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance
9-10 May 2011 | Amsterdam, The Netherlands | ID 11543
November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs
19-20 September 2011 | Paris, France | ID 11530

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
16-18 May 2011 | Location to be confirmed | ID 11527

Pre-Marketing Clinical Safety
4 April 2011 | Basel, Switzerland | ID 11565

DSURs Information Day at the European Medicines Agency
23 March 2011 | London, United Kingdom | ID 11579

EudraVigilance Information Day at the European Medicines Agency
10 May 2011 | London, United Kingdom | ID 11520
15 November 2011 | London, United Kingdom | ID 11522

IDMP Information Day at the European Medicines Agency
16 September 2011 | London, United Kingdom | ID 11524

ICSR Information Day at the European Medicines Agency
5 April 2011 | London, United Kingdom | ID 11523
16 November 2011 | London, United Kingdom | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency
17 November 2011 | London, United Kingdom | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
8 February 2011 | London, United Kingdom | ID 11550
7 June 2011 | London, United Kingdom | ID 11551
13 September 2011 | London, United Kingdom | ID 11552
6 December 2011 | London, United Kingdom | ID 11553

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

REGISTRATION FORM

EudraVigilance Information Day
10 May 2011 | European Medicines Agency, London, UK

ID # 11520

DIA www.diahome.org

Registration includes participant material, coffee breaks and sandwich lunch. Each event is limited to 120 participants.

Standard fee	€ 300.00 ❑
Reduced Fee for Academia and Full Government	€ 150.00 ❑

NOTE: PAYMENT OF REGISTRATION FEES MUST BE RECEIVED BEFORE COMMENCEMENT OF THE COURSE

TOTAL AMOUNT DUE: €_____ NOTE: PAYMENT IS DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION 11520DIAWEB

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

*For company billing, please add your company's VAT number:*_____

If you wish to be billed privately, please contact our Customer Services Team, as below

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred 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

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, 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. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 11582 as well as the invoice number to ensure correct allocation of your payment.
Payments must be net of all charges and bank charges must be borne by the payer.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00
Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA Europe Postfach, 4002 Basel, Switzerland