13th EudraVigilance Information Day

Course #12534
5 October 2012
European Medicines Agency, London, UK

Programme Committee

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

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

Gaby Danan
Pharmacovigilance Expert, FR

Anja van Haren
EudraVigilance Coordinator, Medicines Evaluation Board (MEB), NL

Learning Objectives

At the conclusion of this course, participants should be able to:

- Share knowledge about the implementation of the new pharmacovigilance legislation
- Understand pharmacovigilance and quality systems and the new requirements related to the PSMF
- Discuss the principles of PSUR synchronisation and work sharing in the context of the GVP module VII
- Understand the new signal management activities in the context of GVP module IX
- Share knowledge of the latest developments in relation to the ICH E2C, E2B and M5 topics
- Describe the next steps in providing access to adverse reaction data held in EudraVigilance

Details of the Information Day

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

Capacity: The event is limited to 120 participants

Highlights of the new Pharmacovigilance legislation, EudraVigilance and adverse drug reaction reporting in the EU

Need for this EudraVigilance Information Day

The first set of Good Pharmacovigilance Practices (GVP) modules, together with the Commission Implementing Regulation (EU) 520/2012 on the performance of pharmacovigilance activities published in June 2012, promote and protect public health by strengthening the European system for monitoring the safety and use of medicines. This framework provides important technical and operational details that need to be taken into account by marketing authorisation holders, national competent authorities and the European Medicines Agency in the daily practice of applying the new legislation.
This Information Day provides a forum to update stakeholders about the latest developments with regard to the implementation of the new pharmacovigilance legislation in the broader context of EudraVigilance and adverse drug reaction reporting in the EU. The latest developments in relation to international harmonisation and standardisation activities will be also addressed.

Key Topics

The programme will address the following areas:

- Status of the implementation of the new pharmacovigilance legislation
- The European database of suspected adverse reaction reports
- Highlights of:
  - GVP Module I – Pharmacovigilance systems and their quality systems
  - GVP Module II – Pharmacovigilance system master file (PSMF) in practice
  - GVP Module VI – Management and reporting of adverse reactions to medicinal products, including reporting requirements by Member States during the transitional phase
  - GVP Module VII – Periodic safety update report (PSUR), synchronisation and work-sharing
  - GVP Module IX – Signal management from an EMA and Member State perspective
- International harmonisation and standardisation and latest news on
  - ICH E2C(R2) “Periodic Benefit Risk Update Report” topic
  - ICH E2B(R2) “Individual Case Safety Report” (ICSR) topic
  - ICH M5 “Identification of Medicinal Products” (IDMP) topic

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

Who Will Attend

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

- Pharmacovigilance
- Clinical Development
- Information Management
- Safety databases

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FRIDAY | 5 OCTOBER 2012

08:15 REGISTRATIONS

08:45 Welcome and Key Note

IMPLEMENTATION OF THE NEW PHARMACOVIGILANCE LEGISLATION

The European Medicines Agency, which is responsible for implementing much of the new legislation, has developed a framework for compliance and delivery of strategic requirements. This key note presentation will provide an overview both of the implementation of the pharmacovigilance legislation by the European Medicines Agency and of next steps.

Peter Arlett, EMA, EU

The Implementation of the new Pharmacovigilance Legislation from a Pharmaceutical Industry Perspective

The new pharmacovigilance legislation has significant implications for applicants and holders of marketing authorisations in the EU. This presentation will provide an overview of the initial implementation experience to date from a pharmaceutical industry perspective.

Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott Laboratories Ltd., UK

The European Database of Suspected Adverse Reaction Reports – Initial experience and extension to all active Substances reported in ICSRs

This presentation will provide an overview of the initial experience gained since the launch of the new website on 31 May 2012, one of the Agency's continuing efforts to ensure EU regulatory processes are transparent and open. The planned next steps towards the extension of access to all active substances, which are subject to adverse reaction reports submitted to EudraVigilance, will be also addressed.

Francois Domergue, EMA, EU

10:30 COFFEE BREAK

11:00 Session 1

HIGHLIGHTS OF THE NEW GOOD PHARMACOVIGILANCE PRACTICES

Session Co-chairs: **Anja van Haren**, MEB, NL
Sabine Brosch, EMA, EU

This session will provide participants with an overview of the main requirements defined in the GVP modules I, II, VI and IX, as well as an opportunity to raise practical implementation questions.

GVP Module I – Pharmacovigilance Systems and their Quality Systems
Priya Bahri, EMA, UK

How to apply the GVP Module II – Pharmacovigilance System Master File (PSMF) in Practice
Anya Sookoo, GCP Compliance Unit, MHRA, UK

GVP Module VI – Management and Reporting of Adverse Reactions to Medicinal Products including Reporting Requirements by Member States during the Transitional Phase
Gilles Touraille, EMA, EU
Discussant: EMA representative invited

GVP Module IX – Signal Management from an EMA and Member State Perspective
Sabine Straus, MEB, NL
Discussant: Xavier Kurz, EMA, EU and Georgy Genov, EMA, EU

13:00 SANDWICH LUNCH

14:00 Session 2

GVP MODULE VII – PERIODIC SAFETY UPDATE REPORT (PSUR), SYNCHRONISATION, WORK-SHARING AND THE ICH E2C(R2) DRAFT GUIDELINE

Session chair: **Almath Spooner**, Vigilance Assessment Manager, IMB, IRL

This session will focus on the explanation of the new PSUR synchronisation and work sharing principles and the operational aspects outlined in GVP module VII. The ongoing international harmonisation work towards the finalisation of the new ICH E2C Periodic Benefit Risk Update Report guideline will be also presented.

GVP Module VII – Periodic Safety Update Report (PSUR)
Rodrigo Postigo, EMA, EU

PSUR Work Sharing
Ms Anne Ambrose, Vigilance and Risk Management of Medicines, MHRA, UK

ICH 2EC (R2) draft Guideline: Update on the Periodic Benefit-Risk Report based on Step 2 of the ICH Process
Almath Spooner, Vigilance Assessment Manager, IMB, IRL

15:30 COFFEE BREAK

16:00 Session 3

UPDATE ON INTERNATIONAL HARMONISATION ACTIVITIES IN RELATION TO ICH E2B AND ICH M5

The EudraVigilance Information Day will close with an update on the activities of the ICH E2B Expert Working Group, which is aiming to finalise the Individual Case Safety Report Implementation Guide by November 2012. Furthermore, progress made in relation to the drafting of ICH M5 Implementation Guideline and the development of related messaging standards will be also presented.

Update on the Finalisation of the ICH E2B(R3) draft Implementation Guide
Anja van Haren, EudraVigilance Coordinator, MEB, NL

Update on the ICH M5 Activities
Sabine Brosch, EMA, EU

17:00 END OF THE EUDRAVIGILANCE INFORMATION DAY

HOTEL INFORMATION

Attendees have to make their own reservation.
Recommended hotel close to the EMA:

Hilton London Docklands Riverside
265 Rotherhithe Street,
London , SE16 5HW,
United Kingdom

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 to the EudraVigilance training course.
Room rate is GBP 145.00 (2012 rate) per room incl. breakfast excl. VAT

Please **click here** to book your accommodation at the designated hotel. In order to profit from our special rate we would kindly ask you to use our corporate 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).

DIA 2012 Training Courses in Safety and Pharmacovigilance

Benefit/Risk Management
15–16 October 2012 | Paris, France | ID 12594

How to Prepare for Pharmacovigilance Audits and Inspections
15-16 November 2012 | Prague, Czech Republic | ID 12575

IDMP Information Day at the European Medicines Agency
4 December 2012 | London, United Kingdom | ID 12536

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
16 October 2012 | London, United Kingdom | ID 12539
13 November 2012 | London, United Kingdom | ID 12540

Introduction to Signal Detection and Data Mining in Pharmacovigilance
14-15 November 2012 | Prague, Czech Republic | ID 12574

Medical Approach in Diagnosis and Management of ADRs
15–16 October 2012 | Paris, France | ID 12565

EudraVigilance (EV) - Electronic reporting of ICSR
eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org > Meetings & Training > Find Meetings & Training > Click on EudraVigilance > Search

ABOUT DIA

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REGISTRATION FORM

EudraVigilance Information Day
5 October 2012 I European Medicines Agency, London, UK

DIA www.diahome.org
ID #12534

Fees

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

Registration fees are inclusive of Sandwich lunch and coffee breaks.

Please advise your European VAT number: _____

TOTAL AMOUNT DUE: _____

Payment due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Adress

Postal Code City

Country

Telephone

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Email*

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

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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❑ **Cheques:** Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Küchengasse 16, 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." Please include your name, company, Event ID #12534 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

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.

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

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 100.00.
- Tutorial cancellation: € 50.00.

If you do not cancel five working days prior to the event 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.

All registrations received at DIA Europe Office by 18:00 CET on 21 September 2012, will be included in the Attendee List.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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